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MEMORANDUM FOR AFIT/CIMI
ATTENTION MAJ SALVATORE RUSSO
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FROM: Capt Lauren F. Aase
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SUBJECT: Thesis Submission

Dear Sir:

Enclosed is a copy of my thesis entitled, "The Effects of Disease Management on Glycemic Control and Adherence to American Diabetes Association Guidelines in an Air Force Population."

I am submitting it to AFIT as a part of the AFIT requirements for sponsorship of my educational studies in the Family Nurse Practitioner Program at the Uniformed Services University of the Health Sciences, Graduate School of Nursing, Bethesda, MD.

Respectfully Submitted,

Lauren F Aase

LAUREN F AASE, Capt, USAF, NC
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THE EFFECTS OF DISEASE MANAGEMENT ON GLYCEMIC CONTROL AND ADHERENCE TO AMERICAN DIABETES ASSOCIATION GUIDELINES IN AN AIR FORCE POPULATION

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ABSTRACT

Diabetes has a profound and widespread effect on the medical and financial well-being of this country. Healthcare providers are not always aware of, nor do they always comply with the American Diabetes Association's (ADA) published practice guidelines for diabetic care. To improve patient care, the United States Air Force, as well as many civilian medical care facilities, have implemented a primary care approach to diabetes care based upon continuous quality improvement principles called Disease Management. This quasi-experimental study employed a pre/post-intervention design to compare the effectiveness of traditional primary care with disease management care in achieving glycemic control and adherence to American Diabetes Association guidelines in 28 type1 and type 2 diabetes patients at an Air Force family medicine clinic. Content validity testing on the study instrument designed for this study showed a content validity index of 0.95. There was a high degree of correlation on intra-rater and inter-rater reliability tests of the instrument. Non-significant improvements in glycemic control were found in disease management care compared with traditional care. Disease management improved compliance in all 18 adherence to ADA guideline indicators studied, with significant improvements in nutritional assessment 25.0% ($p = 0.009$), exercise addressed 26.8% ($p = 0.006$), annual foot exams 39.3% ($p = 0.001$), annual urine microalbumin screening 32.1% ($p = 0.004$), annual lipid screening 28.5% ($p = 0.02$), comprehensive diabetes education 28.6% ($p = 0.008$), baseline EKG 42.8% ($p < 0.001$), and tobacco and alcohol assessment 33.9% ($p < 0.001$). Study findings add to the current body of nursing knowledge regarding diabetes care.

Key Words: **continuous quality improvement** **disease management** **quasi-experimental** **pre/post intervention design** **disease management care** **traditional primary care** **glycemic control** **compliance** **adherence** **American Diabetes Association Guidelines** **type 1 diabetes** **type 2 diabetes** **Air Force**

THE EFFECTS OF DISEASE MANAGEMENT ON GLYCEMIC CONTROL AND ADHERENCE TO AMERICAN DIABETES ASSOCIATION GUIDELINES IN AN AIR FORCE POPULATION

by

LAUREN FRANKLIN AASE, BSN

THESIS

Presented to the Graduate School of Nursing Faculty of the

Uniformed Services University of the Health Sciences

in Partial Fulfillment of the Requirements for the

Degree of

MASTER OF SCIENCE

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

May 2001

PREFACE

This research was conducted in an effort to discover any initial evidence supporting the implementation of diabetes disease management programs in the Air Force.

DEDICATION

This work is dedicated to all of the diabetes patients and their families that I have had the privilege to serve over the years since becoming a nurse. They have taught me much about life with diabetes, and learning how to live with diabetes. Special thanks to my father and my grandmother who taught me to laugh with others and at yourself, and not take yourself too seriously. Thanks to my mother for always telling me I can do better. Lastly, I thank my wife Marilou and my children Cara, Link, Nick, Clint, and Mallorie for supporting me and being there for me through the good times and the bad, especially all of the days I've had to put the family "on-hold" to complete school.

"All you need is love, love is all you need" – Lennon / McCartney, Magical Mystery Tour (1967).

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CHAPTER I: INTRODUCTION

Background

Diabetes has a profound and widespread effect on the medical and financial wellbeing of this country. Approximately 15.7 million or 5.9% of the United States population have diabetes with 5.4 million of these remaining undiagnosed. Diabetes is the leading cause of end-stage renal disease, accounting for 40 % of new cases each year. Diabetes is the number one cause of new cases of blindness in people ages 20-74 and the most frequent cause of non-traumatic lower limb amputations. Each year 56,000 amputations are performed upon people with diabetes. Diabetes ranks as the seventh leading cause of death in the United States and the sixth leading cause of death by disease (American Diabetes Association, 1999a).

The cost of diabetes is not limited to human suffering. Direct and indirect healthcare cost estimates range from $92 billion to $138 billion annually in the United States alone. The 1997 per capita costs of healthcare for people with diabetes equaled $10,071 compared to $2,699 for non-diabetics. The prevalence of diabetes increases with advancing age, with people older than 55 representing approximately half of all diabetes cases (American Diabetes Association, 1999a). According to the Bureau of the Census (1995) by the year 2050 the elderly population will have doubled with one in five Americans being elderly. The largest percentage of this growth will occur between 2010 and 2030 as the "baby boom" generation enters the 65 years and older age category. It can be anticipated that as America ages, the healthcare needs and the financial costs associated with diabetes will become an even greater burden to society.

Pathogenesis, Consequences, and Care of Diabetes

Diabetes is a metabolic disorder. Elevated blood glucose levels lead to microvascular and macrovascular manifestations of the disease that are associated with an increase in morbidity and mortality as well as a reduced quality of life (American Diabetes Association, 1999e). Diabetes is associated with a two- to fourfold increased risk of macrovascular diseases such as coronary heart disease (CHD) and other atherosclerotic (plaque-forming) diseases of the major arteries. Macrovascular disease results in myocardial infarction, stroke, and death.

Exposure of body proteins to high levels of glucose, as occurs in poorly controlled diabetes, leads to the formation of advanced glycation end products (AGE) which ultimately result in microvascular disease (Gee, 1998). AGEs are thought to bond to collagen protein capillary walls, forming a glue-like substance that weakens the tissue and causes cell proliferation. The result is a decrease in nutrient exchange, protein leaking, edema and revascularizton. Vessels are weakened from this process and therefore rupture easily. This occurs in diabetic retinopathy, ultimately leading to 12,000-24,000 new cases of blindness due to diabetic retinopathy each year (American Diabetes Association, 1999a). The effects of this process also lead to kidney failure and neuropathy (nerve damage). Neuropathy has been implicated as the cause for atony of the gut (gastroparesis), foot ulcers leading to amputation, urinary bladder dysfunction, male erectile dysfunction, and loss of sensation to the hands and feet, known as peripheral neuropathy (Barker, Burton, & Zieve, 1999).

In pregnancy, diabetes is associated with fetal birth abnormalities, newborn death, macrosomia (large birth weight), hydramnios (excess amniotic fluid), and toxemia of pregnancy. Optimal blood glucose control from conception through birth is essential for the health of the mother and baby (American Diabetes Association, 1999a). The damaging effects of diabetes are extensive and impact upon all age groups.

Several large research studies have demonstrated the importance of tight blood glucose control. Data from these studies have been used by the American Diabetes Association (ADA) to develop and revise the standards of diabetes care. Two landmark studies, the Diabetes Control and Complications Trial (DCCT) (1993) for type 1 diabetes and the United Kingdom Prospective Diabetes Study (UKPDS) (1998) for type 2 diabetes, have been cited by the American Diabetes Association (ADA) as having both clinical and statistical significance. These two studies are widely known in diabetes literature by their abbreviated titles, the DCCT and UKPDS, respectively. Over the study period which averaged seven years, the DCCT demonstrated an approximate 60% risk reduction between the intensive treatment group and the standard treatment cohort in diabetic retinopathy, nephropathy, and neuropathy (American Diabetes Association, 1999d).

The UKPDS results confirmed that tight glycemic control also provides positive end organ effects for type 2 diabetes, showing an overall decrease in microvascular complications by 25%. The study further showed that lowering blood pressure to a mean of 144 / 82 mmHg significantly reduces strokes, diabetes-related deaths, heart failure,

microvascular complications, and visual loss. Current guidelines suggest 120/80 mmHg is optimal and normal is < 130/85 mmHg (American Diabetes Association, 1999e). It follows that if intensive management of diabetes can reduce long-term complications then it will also decrease the costs to society.

The ADA recommends that people with diabetes should receive their care from physician-coordinated teams including, but not limited to, physicians, nurses, dieticians, and mental health professionals with expertise in diabetes. The ADA has established basic standards of care for people with diabetes. These standards of care provide physicians and other health care professionals with a means to set treatment goals, assess the quality of diabetes treatment provided, identify areas where more attention or self-management training is needed, and define timely and necessary referral patterns to appropriate specialists. In addition, they are intended to provide people with diabetes with a means to assess the quality of medical care they receive, develop expectations for their role in the medical treatment, and compare their treatment outcomes with standard goals (American Diabetes Association, 1999g). One method of implementing these recommended treatment teams and standards of care is a concept known as "disease management."

Disease Management

In an effort to control costs while providing quality care for chronically ill individuals, HMOs and other healthcare organizations, including the military, are looking to disease management as a means of treating difficult and "resource-consuming" disorders. Joshi and Bernard (1999) define disease management as "an approach to

delivering population-based, patient-centered care that is based on a platform of continuous improvement"(p. 386). They view disease management as aiming to provide "best practice care" across the continuum, including many different providers and many different sites of care delivery.

Disease management programs typically consist of teams of healthcare professionals that are experts in the field. The teams utilize best practice protocols or "clinical pathways" developed around established standards of care. Improved patient outcomes and cost-efficiency are achieved through "continuous quality improvement" strategies borrowed from the manufacturing industry. Patient data is collected on an ongoing basis and periodically analyzed to assess whether care given is meeting standards of care, or if changes need to be made to improve the process.

Relevance to Nursing

Disease management has an appeal to many health plan administrators because it incorporates targeted treatment, care planning and outcomes measurement, and cost-efficiency. Since these aspects are some of the established strengths of the nursing process, it comes as no surprise that nurses play a key role in disease management programs. Nurses use their unique assessment skills and ability to practice across the continuum of care to help identify individuals appropriate for disease management. Nurses serve as patient educators, care coordinators, case managers, participants in utilization review and outcomes research, and participants in the development of clinical guidelines for patient care (Reeder, 1999).

Because disease management requires learning new processes, it has been criticized for initially slowing down physician productivity. Nurses are often hired to streamline the process by making reminder phone calls to patients, placing relevant algorithms in the medical record, assisting with referrals, and supporting patient education as a means of addressing this issue (Joshi & Bernard, 1999). By taking an active leadership role in disease management, nursing has an opportunity to make a positive impact upon the quality of life of the diabetic population while pioneering efforts to reduce the financial burden of healthcare to society.

Summary

Diabetes is a chronic illness with complications that create significant monetary and physical costs to society and the people who live with it. Studies have shown that intensive blood glucose control and monitoring of diabetic patients can reduce the incidence of these complications. The American Diabetes Association has developed standards of care for effective management of diabetes. Disease management attempts to implement these standards of care in a best practice pattern approach using a coordinated team of health professionals skilled in diabetes care. Studies are needed to determine the effectiveness of disease management in helping diabetics achieve blood glucose control and adherence to ADA standards of care.

Purpose of the Study

The purpose of this study was to compare the effectiveness of the disease management model to the traditional primary care model of patient care in achieving glycemic control and adherence to American Diabetes Association standards of care. The

study took place in one military outpatient clinic setting. Traditional care, as provided to the study group one year prior to its entry into a disease management program, was compared to disease management care after the study group was in a disease management program for one year. Glycemic control was assessed using hemoglobin A1C levels. Adherence to ADA standards was measured with an Adherence to ADA Guidelines Assessment Checklist developed for this study.

Research Questions/Hypothesis

Research Questions

Is there a significant difference in efficacy between the disease management model and the traditional primary care model in achieving glycemic control and adherence to American Diabetes Association standards of care in the Air Force outpatient setting? This research question can be broken into two separate questions. First, is there a significant difference in hemoglobin A1C levels within the study group while in traditional care compared to levels after the group was in disease management? Secondly, is there a significant difference in adherence to ADA standards of care in the study group while in traditional care compared to adherence after the group was in disease management?

Hypotheses

Implementation of a diabetes disease management program in traditional primary care will improve glycemic control and increase adherence to American Diabetes Association Guidelines in the Air Force outpatient setting.

Conceptual Framework

Several concepts are relevant to understanding the scope of this study. The following is a discussion of disease management, standards of care, preventive care, and complications of diabetes. Disease management is a new theoretical model of patient care that is being observed in this study to determine its value in managing complex and problematic disorders such as diabetes or other chronic diseases.

Disease Management Theory

Disease management was previously defined as a care delivery model performing population-based, patient-centered care using best practice protocols with continuous quality improvement (CQI) feedback mechanisms employed to improve patient outcomes and reduce costs. Bodenheimer (1999) describes two different forms of disease management used in the present American healthcare system. One is a contracted "carve-out" model and the other a primary care-based model.

The carve-out version is a commercially sold model that is marketed by various companies nationwide as a means to save their clients money by focusing on high-risk patients and reducing short-term costs. An example would be programs to manage congestive heart failure or asthma to reduce emergency room visits and hospital admissions. Because their focus is on saving money, these programs need to show quick cost savings and therefore they typically avoid managing chronic illnesses such as diabetes or hypertension. It may take years for the costly complications from these chronic diseases to develop, making them unsuitable for showing immediate program benefits.

The other disease management model is a primary care-based model that uses secondary and tertiary prevention strategies, which improve public health through early detection of disease. This primary care-based model of disease management was the focus of this study and was compared to traditional primary care.

Disease management differs from primary care as it is customarily delivered. "Traditional primary care" providers are general practitioners who take a broad perspective on the patient's medical condition rather than focusing on a specific disease or organ system. Patients with complex medical conditions often look to their primary care physician to serve as an advocate, advisor, and coordinator of care delivered by a multitude of specialists (Fihn & McGee, 1992). Traditional primary care providers generally use American Diabetes Association guidelines as their standard of care for their diabetic clientele, similar to disease management providers. They also refer diabetic patients to other health professionals for various specialty care needs.

Disease management differs from traditional primary care because it involves multidisciplinary teams of healthcare professionals with expertise in managing diabetes, including the patient's primary care physician. These providers work collaboratively to identify the most desirable program of care for the patient using prevailing current guidelines (in the form of clinical pathways). A nurse case manager may be the focal hub that coordinates the efforts of the team and oversees the CQI aspects of the program.

Physician and patient commitment is critical to any program. Often, physician practice variation can be an obstacle to implementation of new care standards if the physician disputes the validity of measurement tools, data, or current guidelines. Patients

may be unaware of changes in care or available alternatives, and resist compliance to modifying behaviors (Brunner & Hickey, 1997). Primary care physicians may find it difficult to stay abreast of the latest treatment advances in every disease, whereas teams focusing on the management of one disease entity may be more likely to be attuned to the latest developments. Teams sharing the same philosophy, treatment goals, and standards are likely to foster patient confidence and enhance compliance.

Disease management utilizes advanced information systems capable of collecting data and measuring patient outcomes. Outcome data provides feedback to staff and providers to target actionable areas for process improvement. "Thus a successful disease management approach builds on learning and, in traditional CQI fashion, incorporates those learnings for improvement in the programs and ultimately results in improvement in patient outcomes" (Joshi & Bernard, 1999, p. 391).

Common components that are found separately in all disease management programs include: "patient and family education; provider education; health risk assessment and stratification; preventive services and wellness activities; clinical guidelines, protocols and algorithms; case management; home care services; clinical information systems and decision support; and outcomes tracking and reporting, practice profiling, and feedback" (Joshi & Bernard, 1999, p. 385). Combining these components together into a single program focusing on improving the health of a population produces a product with synergistic value to the customer.

Certain factors must be considered while determining the appropriateness of a disease entity for disease management programs. Gunter, Byrnes, Shainline, and Lucas

(1996)) stated that at least two of the following five criteria were necessary to be included in Lovelace Health System's Episodes of Care disease management programs:

- high patient volume,
- high overall cost,
- high variation in care delivery,
- high risk to patients, and
- projected ability to make significant improvements.

Based upon these criteria, an argument can be readily made for inclusion of diabetes in a disease management scheme based upon the numbers of patients, the risks to patients in regard to complications, potential for significant improvements identified by the DCCT and UKPDS studies, and in costs to the healthcare system already described. A potential for variation in care delivery exists due to the number of recent advancements made in diabetes care.

Brunner and Hickey (1997) summarize benefits of the birthing Episodes of Care disease management program as "successful redesign of maternity care, improved patient outcomes and physician satisfaction, and cost reduction for the system" (p. 257). Other benefits of disease management can be inferred from the University of Pennsylvania Health System Disease Management Scorecard. Service (patient and physician satisfaction), clinical quality (number of clinical indicators with improvement), access (number of programs implemented and patients enrolled), and value (reduction in costs per patient per month) are listed as key performance areas for measuring success (Joshi & Bernard, 1999).

In order to realize these benefits it follows that goals for an effective disease management program should include at a minimum:

- identification of patients at risk and facilitating participation into the program,
- improvement of patient clinical outcomes,
- development and improvement of best practice guidelines for care,
- improvement of patient and healthcare provider satisfaction, and
- reduction of costs for healthcare (both short-term and long-term).

Standards of Care

Standards of care are an essential concept to this study. Standards of care serve several functions. In legal practice they define accepted norms of practice to which health care providers are obligated to adhere in order to remain clear of liability in malpractice suits. State legislatures pass nursing practice acts that define scope of practice for nurses within that state. Employment institutions have written policies and procedure that detail how care is to be performed at that facility (Potter & Perry, 1985). In this study, standards of care refer to American Diabetes Association guidelines, Standards of Medical Care for Patients with Diabetes Mellitus (American Diabetes Association, 1999g).

Preventive Care

Preventive care can be divided into three stages on a continuum. Primary prevention prevents the disease from occurring; secondary prevention detects disease that is present but has not manifested itself clinically and uses measures to slow onset of clinical expression; and tertiary prevention attempts to limit complications once disease has become clinically evident (Barker et al., 1999). While public education efforts by the

medical community attempt to prevent the onset of diabetes, the secondary and tertiary prevention measures are the ones targeted by disease management. ADA screening criteria help identify individuals appropriate for disease management, position them on the prevention continuum, and evaluate disease progression. Best practice protocols in tertiary prevention aim to minimize or postpone disability, morbidity, and death.

Complications of Diabetes

Chronic hyperglycemia from diabetes is associated with long-term damage and failure of certain body organs, especially the eyes, heart, kidneys, nerves, and blood vessels. While type 1 diabetics generally do not have pre-existing diabetic complications at diagnosis, type 2 diabetics often do. End organ disease is known to develop years prior to the diagnosis of type 2 diabetes (American Diabetes Association, 1999f).

Because of the complexity of the disease, secondary and tertiary prevention often occur concurrently. Secondary measures such as detection and treatment of hypertension in turn act as primary measures to prevent the onset of renal disease and retinopathy.

Microalbuminuria (30-300 mg/day) is the earliest clinical evidence of nephropathy. Approximately 80 percent of subjects with type 1 diabetes with sustained microalbuminuria will have increased urine albumin excretion at the rate of about 10 – 20% per year progressing to overt nephropathy (> 300 mg / 24 hours). End-stage renal disease (ESRD) will follow in approximately 50% of these individuals within 10 years. Because diabetes is usually present for many years before diagnosis, a higher proportion of type 2 diabetics demonstrate microalbuminuria and overt nephropathy shortly after diagnosis. This is strong evidence of the importance of early screening for

persons at risk for type 2 diabetes as well as the need for aggressive screening and treatment of complications. The ADA recommends annual screening for proteinuria/microalbuminuria with specific recommendations for confirmation and treatment (American Diabetes Association, 1999c).

Hypertension is present in one-third of patients newly diagnosed with type 2 diabetes. The common association of simultaneous glucose intolerance, hypertension, elevated LDL cholesterol and triglycerides, lowered HDL cholesterol, obesity, and susceptibility to coronary artery disease is often called "syndrome-x" and may indicate common etiological mechanisms (American Diabetes Association, 1999c). In a seven-year study of 1373 nondiabetic and 1059 diabetic subjects comparing incidence of myocardial infarction, Haffner, Lehto, Ronnemaa, Pyorala, and Laasko (1998) found that diabetics with no prior myocardial infarction at baseline had the same risk as non-diabetics with a prior history of myocardial infarction. The risk for having another event was found to be 20.2% vs. 18.8%, respectively ($p < 0.001$). The authors conclude that these data suggest that all persons with diabetes could be treated as if they had prior coronary disease.

ADA standards of care reflect this conclusion in regards to lipid screening and management suggestions. Even for patients without known coronary heart disease (CHD) or peripheral vascular disease (PVD), the ADA recommends that the optimal low density lipoprotein (LDL) levels for diabetics is 100 mg/dl. Dietary therapy is to be initiated above 100 mg/dl. Drug therapy is recommended at levels $\geq$ 130 mg/dl, with LDL goal remaining $\leq$ 100 mg/dl.

Evidence-based standards of care such as these are the secondary and tertiary prevention mechanisms of the disease management model of care. The CQI aspects of disease management provide the mechanism for modifying and improving these standards of care when new data supports change. By comparing outcome measures such as hemoglobin A1C levels and adherence to ADA guidelines (standards of care) following the implementation of a disease management program, this study endeavored to show the effectiveness of disease management as a tool to improve the quality of diabetes care and reduce the costs of diabetes.

Definitions and Variables

Disease Management

Conceptual definition. "An approach to delivering population-based, patient-centered care that is based on a platform of continuous quality improvement" (Joshi & Bernard, 1999, p. 386).

Operational definition. As it applies to this study, disease management is a primary care healthcare delivery approach consisting of a multidisciplinary team of healthcare providers working together in a collaborative manner. All team members utilize the same treatment guidelines and established protocols, and maintain a database for continuous quality improvement purposes. Disease management is the type of care that was compared to traditional primary care.

Traditional Primary Care

Conceptual definition. Traditional primary care providers are defined as general practitioners who take a broad perspective on the patient's medical condition rather than

focusing on a specific disease or organ system. For complex diseases, such as diabetes, the primary care physician acts as advisor, advocate, and coordinator of care (Fihn & McGee, 1992). Traditional primary care is the patient services provided by such a provider.

Operational definition. In this study, traditional primary care is the patient services provided by physicians in the family medicine clinic at the study facility for their diabetic clients prior to the application of a disease management program. Traditional primary care is a research variable being compared to the patient care after implementing a disease management program.

Type 1 Diabetes

Type 1 diabetes is a disorder characterized by complete destruction of the beta cells in the pancreas leading to absolute insulin deficiency. Individuals require insulin administration (by injection or pump) in order to utilize glucose (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 1999).

Type 2 Diabetes

Type 2 diabetes is caused by either predominantly insulin resistance with relative insulin deficiency, or predominantly an insulin secretory defect with a degree of insulin resistance. It is an insidious disease that often goes undetected for years. Complications from sustained hyperglycemia often develop during this undiagnosed period (Expert Committee on the Diagnosis and Classification of Diabetes Mellitus, 1999).

Body Mass Index

Jarvis (1996) defines Body Mass Index (BMI) as "a simple indicator of total body fat or obesity" (p. 144). BMI is used by many diabetes practitioners as a means to assess obesity in their clients. BMI is calculated by patient weight in kilograms divided by height in meters squared. A BMI of 27 or greater indicates obesity. Although BMI assessment is not part of the adherence portion of this study, height and weight information were collected during data collection. BMI was calculated from these data to describe the population pre- and post-disease management.

Healthcare Providers

Healthcare providers refer generally to any medical professional. For the purposes of this study, it includes all multidisciplinary team members: physicians, nurse practitioners, physician assistants, dieticians, staff nurses, optometry personnel, and laboratory specialists.

American Diabetes Association

The American Diabetes Association is a non-profit organization whose stated mission "is to prevent and cure diabetes and to improve the lives of all people affected by diabetes. To fulfill this mission, the American Diabetes Association funds research, publishes scientific findings, and provides information and other services to people with diabetes, their families, healthcare professionals and the public" (American Diabetes Association, 1999b).

American Diabetes Association Guidelines

Conceptual definition. ADA guidelines refer to the standards of care for diabetes as published by the American Diabetes Association (1999).

Operational definition. In relation to this study, these include the minimum standards identified by the American Diabetes Association (1999) for nutritional counseling, exercise counseling, weight measurement, blood pressure measurement, hemoglobin A1C measurement and patient goal levels, comprehensive foot examination, dilated eye/visual examination, microalbuminuria screening, lipid screening, patient self-management education, self-monitored blood glucose testing, baseline EKG measurement, and frequency of diabetes follow-up examinations. Also included are the minimum standards identified by the American Diabetes Association (2000) for influenza vaccination, pneumococcal vaccination, and tobacco and alcohol assessment. Adherence to ADA guidelines is a dependent variable that was measured and quantified for comparison within the study group prior to and after implementation of a disease management program.

Clinical Pathway

A "Clinical Pathway" is synonymous with "Critical Pathway" and "Clinical Practice Guidelines." These terms are used interchangeably in the literature. All refer to the "best practice protocols" previously discussed under Disease Management. The Clinical Pathway is a set of written guidelines that are meant to guide healthcare providers in the care of specific disease entities. They identify the appropriate interventions needed to

meet prevailing standards of care. The study group utilizes this type of document for diabetes care. A copy is included in Appendix A.

Glycemic Control

Conceptual definition. Glycemic control refers to how well the patient is able to keep blood glucose levels within normal ranges, 70 to 140 mg/dl before meals; below 180 to 200 mg/dl after meals (Franz, Etzwiler, Joynes, & Hollander, 1991). This can be measured in the short term by self-monitored blood glucose (SMBG) testing and lab tests for blood plasma glucose levels.

Operational definition. For the purposes of this study, glycemic control was measured by glycated hemoglobin levels (hemoglobin A1C). This is a measure of the amount of glucose bound to hemoglobin in the erythrocytes. The hemoglobin A1C reflects the glucose control over the 2-3 month lifetime of the average erythrocyte. Non-diabetic hemoglobin A1C (HbA1C) values range from 4.0-6.0%. Goals for glycemic control are HbA1C < 7% with action suggested for HbA1C > 8%. Risk for hypoglycemia or presence of comorbid conditions may necessitate individualizing goals (American Diabetes Association, 1999g). Glycemic control is a dependent variable that was measured and compared in the study group prior to and following implementation of the disease management program.

Intensive Management

"Intensive management" or "tight control" refers to keeping blood glucose levels as close as possible to normal levels. In patients on insulin therapy this may necessitate multiple injections (three or more daily) or treatment with an insulin pump. "In type 2

diabetes, medical nutrition therapy, exercise, and oral glucose-lowering drugs may achieve tight control, but insulin is often required" (American Diabetes Association, 1999d, p. S24).

Assumptions

Reeder (1999) provides some basic assumptions that underlie disease management:

- Approximately 20% of the population accounts for 80% of health care expenditures.
- Measures such as preventive and ongoing care that improve the patient's quality of life cost less than handling more acute illness in an advanced disease state.
- A multidisciplinary team across the continuum of care can best manage complex medical conditions.
- An identified population currently experiences huge variations in treatment and outcomes.
- An optimal way to treat patients exists to decrease that variation, improve quality, and lower cost.
- Assertive, empowered consumers take a more active role in their care (p. 41).

It is assumed that disease management principles and ADA standards of care will have the same effects and implications for military populations as for civilians. It is assumed that any effects on HbA1C values and adherence to ADA guidelines were attributable to the implementation of the disease management program and not from maturation of the sample.

Limitations

This researcher recognizes the following limitations to this study:

- Because military personnel are routinely transferred to new duty stations, there is no guarantee that disease management team membership remained constant through the study.
- Sample attrition may have occurred due to military transfers.
- Incomplete documentation in the medical records may have limited the accuracy of data collected. Charts may have not documented care provided at sites outside of the primary care facility. Chart review may reflect a measure of quality of charting rather than quality of care rendered.
- Charts of military beneficiaries are sometimes kept in their own possession and therefore some were not available for data collection.

Despite these limiting factors, this study will contribute to the body of knowledge concerning multidisciplinary team practices and care outcomes for patients with diabetes who are being managed using the disease management approach.

CHAPTER II: LITERATURE REVIEW

Introduction

This chapter examines the literature to provide further background for the study concepts and identifies previous studies related to disease management. The literature will be summarized and its relationship to the present study analyzed. Finally, a description of how this study will contribute to the body of current nursing knowledge will be offered. Topics reviewed in the literature include: comparison of military and civilian diabetes populations, benefits and adverse effects of intensive therapy for diabetes complications, cost savings from tight glycemic control, need for improved diabetes care, diabetes interventions in the literature, and assessment tools for measuring compliance with American Diabetes Association Standards of Care.

Comparison of Military and Civilian Diabetes Populations

Prevalence of Type 1 Diabetes in Civilian and Military Populations Compared

In order to gauge the relevance and generalizablity of this study, we need to compare the prevalence of diabetes in the military population with the civilian population upon which most of the literature is based. Tiwary and Michalek (1995) retrospectively studied the incidence of type 1 diabetes among dependent children, age 21 or younger, of U.S. active duty personnel admitted to U.S. Army medical treatment facilities worldwide from fiscal years 1971-1991. Patient data were provided by the Directorate of Patient Administration Systems and Biostatistics Activities, Fort Sam Houston, Texas. The authors assumed that patients admitted to Army facilities would approximate the rates of the other service branches. After factoring for patients leaving the system due to death or

parents leaving the military, records indicated diagnosis of type 1 diabetes in 2,308 patients out of a total of 522,326, or about 0.44%. The overall incidence for the 20-year study period was 16.2 per 100,000 person-years (95% Confidence Interval, 15.5-16.9).

Tiwary and Michalek (1995) thought the incidence of diabetes in this population was lower than the national incidence, although no published data on national rates were available at the time of the study. The American Diabetes Association (1999a) puts numbers of type 1 (juvenile-onset) diabetes at 5%-10% of all diabetics, and all diabetics at 5.9% of the general population. Using the ADA percentage estimate of type 1 diabetics (5% - 10%), 5% - 10% of 5.9% equals 0.3%- 0.6%, a rough estimate of the general population who are type 1 diabetics. This would seem to differ with the authors' belief that the numbers of military type 1 diabetics in the study (0.44%) may be lower than national rates. The numbers appear to indicate that, for the purposes of this study, the incidence of type 1 diabetes in both the civilian and military populations is similar.

Prevalence of Type 2 Diabetes in Civilian and Military Populations Compared

In a survey of 1,610 asymptomatic active duty army soldiers reporting for pre-training physicals, Chapin, Medina, Le, Bussell, and Bussell (1999) examined the prevalence of undiagnosed diabetes (plasma glucose 200 mg/dl two hours after a 75 gram glucose load), impaired glucose tolerance (140-199 mg/dl two hours after a 75 gram glucose load), and impaired fasting glucose (110-125 mg/dl) among U.S. soldiers, based upon World Health Organization (WHO) criteria. Of the 1502 (93% of the total reporting) who agreed to participate in the study, 781 volunteered for glucose testing, while 721 consented only to fill out a risk questionnaire. The balance (7%) were excluded

due to prior diagnosis of diabetes or failure to report for lab testing. Study volunteer ages averaged 32 $\pm$ 9 years.

The National Health and Nutrition Examination Survey (NHANES III, 1988-1994) (Harris et al., 1998) excluded military personnel by design and reported national rates of civilians with undiagnosed diabetes at 4.3%-6.3%, the rate of impaired glucose tolerance at 15.6 %, and impaired fasting glucose at 10.1 %. In comparison, Chapin et al. (1999) found prevalence rate of undiagnosed diabetes in their study sample of military personnel to be 0.5 %, 95 % confidence interval (CI) 0.1-1.4. The sample rate of impaired glucose tolerance was 1.8% (95% CI 0.9-3.3) and the impaired fasting glucose rate was 1.0% (95% CI 0.4-2.2). These sample rates of undiagnosed diabetes, impaired glucose tolerance, and impaired fasting glucose were approximately one-tenth that of the national rates for civilians as compared to the NHANES III data (Harris et al., 1998). Nonetheless, the study shows that undiagnosed diabetes existed even in a predominantly young, non-obese, and physically fit population of active duty military, although at a lesser prevalence than in the civilian population.

Civilian and Military Demographic Features and Diabetes-Related Diagnoses Compared

Jackson, Strong, Cheng, and Meyer (1999) compared demographic features, diagnoses, and procedures in civilian and military ambulatory internal medicine clinics. Using one year's data (September 1996 to August 1997) from the Ambulatory Data System (ADS) in an adult primary care clinic at Madigan Army Medical Center and data from the 1995 National Ambulatory Medical Care Survey (NAMCS) (as cited in Jackson et al., 1999), the authors compared a total of 26,944 military patient encounters to

NAMCS civilian data. Patients were similar in age, with civilians averaging 54.5 years of age and military patients averaging 53.5 years. Of the top 35 diagnostic groupings between military and civilians, diabetes ranked second (6.24 %) and third (4.82 %), respectively. Essential hypertension ranked first in both groups (17.39 % and 9.9 %, respectively). Hyperlipidemia was fourth (4.71 %) and seventh (3.21 %), respectively. Atherosclerotic coronary artery disease ranked tenth (2.16 %) for military patients and sixth (3.5 %) for civilians.

There was no statistical difference between the rankings of military and civilian diagnostic groups (Spearman's $p = 0.87$). The relationship between the two practice group proportions was linear ($p < 0.0001$) with 84 % of the variance between practices explained by the diagnostic groupings. Both groups were strikingly similar and it is interesting that the "syndrome-x" disorders (diabetes, hypertension, hyperlipidemia, and atherosclerotic coronary artery disease) are ranked so close together in both groups, indicating the strong relationship between diabetes and these well-known complications of uncontrolled diabetes (Jackson et al., 1999).

These three studies show military and civilian populations to be more similar than different. There does appear to be a smaller proportion of diabetes and undiagnosed diabetes among dependent children and asymptomatic adults in the military population. Study design limitations or differences in sample characteristics may account for these differences. Research findings, diagnostic tools and criteria, and patient care interventions also appear to be similar between civilian and military populations. However, generalizations between the two populations must be made with caution.

Benefits and Adverse Effects of Intensive Therapy for Diabetes Complications

Intensive Therapy Benefits in Type 1 Diabetes

The significance of the devastating effects of diabetic complications was discussed in Chapter I of this proposal. In a classic study of 1441 patients with type 1 diabetes, the Diabetes Control and Complications Trial Research Group (1993) prospectively investigated the effects of glycemic control on the development and progression of diabetic retinopathy in the Diabetes Control and Complications Trial (DCCT). The major inclusion criteria included insulin dependence (as evidenced by deficient c-peptide secretion), age 13 to 39 years; and absence of hypertension, hypercholesterolemia, and severe diabetic complications or medical conditions.

Although principally designed to provide information about retinopathy, the DCCT 1993) researchers also studied renal, neurologic, cardiovascular, and neuropsychological outcomes and the adverse effects of two therapies. At baseline, 726 patients with no retinopathy (the primary prevention cohort) and 715 patients with mild retinopathy (secondary prevention cohort) were randomly assigned to either the intensive therapy or conventional therapy group. Primary prevention cohort conventional therapy patients ($n = 378$) were a mean age of 26 ± 8 years, 54% were male, 96% were of the white race, mean HbA1C was $8.8\% \pm 1.7$, and duration of type 1 diabetes was 2.6 ± 1.4 years. Primary prevention cohort intensive therapy group patients ($n = 348$) were a mean age of 27 ± 7 years, 49% were male, 96% of the white race, mean HbA1C was $8.8\% \pm 1.6$, and duration of type 1 diabetes was 2.6 ± 1.4 years. Secondary prevention cohort conventional therapy patients ($n = 352$) were a mean age of 27 ± 7 years, 54% were male,

97% of the white race, mean HbA1C was 8.9% ± 1.5, and duration of type 1 diabetes was 8.6 ± 3.7 years. Secondary prevention cohort intensive therapy patients (n = 363) were a mean age of 27 ± 7 years, 53 % were male, 97% of the white race, mean HbA1C was 8.9% ± 1.5, and duration of type 1 diabetes was 8.9 ± 3.8 years. All "±" values above are means ± standard deviation (SD).

Intensive therapy involved managing blood glucose levels as closely as possible to non-diabetic levels. Non-diabetic parameters included preprandial blood glucose levels between 70-120 mg/dl and HbA1C levels < 6.05 %. Intensive therapy interventions included three or more injections of insulin daily or use of an insulin pump with dose adjustments based upon self-monitored blood glucose testing (SMBG) that were performed four or more times daily. Conventional therapy consisted of one or two daily insulin injections, daily SMBG or urine glucose testing, and education regarding diet and exercise. After following the two cohorts an average of 6.5 years (range 3-9 years) the results were so convincing that the independent data monitoring committee determined the study data warranted terminating the trial (Diabetes Control and Complications Trial Research Group Research Group, 1993).

Retinopathy benefits. In the primary prevention cohort, the adjusted mean risk for developing retinopathy was reduced through intensive therapy by 76% (95 % CI, 62-85) over the conventional group ($p < 0.001$). In the secondary prevention group, intensive therapy slowed progression of retinopathy by 54% (95% CI, 39-66) compared with the conventional therapy group ($p < 0.001$) (Diabetes Control and Complications Trial Research Group Research Group, 1993).

Nephropathy benefits. In the combined cohorts, intensive therapy reduced the occurrence of microalbuminuria (urine albumin excretion $\geq$ 40 mg/24 hours) by 39% (95% CI, 21-52) over conventional therapy ($p \leq 0.002$), and albuminuria (urine excretion $\geq$ 300 mg/24 hours) by 54% (95% CI, 19-74) over conventional therapy ($p < 0.04$) (Diabetes Control and Complications Trial Research Group Research Group, 1993).

Neuropathy benefits. Clinical neuropathy in the combined intensive cohorts was reduced by 60% (95% CI, 38-74) over the combined conventional groups ($p \leq 0.002$) (Diabetes Control and Complications Trial Research Group Research Group, 1993).

Macrovascular disease benefits. The relative youth of subjects (13 to 39 years) precluded detection of macrovascular events. However, intensive therapy reduced the development of LDL cholesterol >160 mg/dl by 34% (95% CI, 7-54) in the combined cohorts ($p = 0.02$) (Diabetes Control and Complications Trial Research Group Research Group, 1993).

Glycemic control benefits. The mean blood glucose profile for the intensive therapy group was 155 $\pm$ 30 mg/dl (approximate equivalent relationship to HbA1C is 7%) compared to 231 $\pm$ 55 mg/dl (approximate equivalent relationship to HbA1C is 9.5%) in the conventional treatment group ($p < 0.001$) (Diabetes Control and Complications Trial Research Group Research Group, 1993).

Adverse Effects of Intensive Therapy in Type 1 Diabetes

Some adverse side effects were noted with the intensive therapy by the DCCT researchers (1993). There was an initial transient worsening of retinopathy in the intensive therapy group that resolved by 18 months and followed with a 74% (95% CI,

46 - 88) subsequent reduction in disease progression over the conventional therapy group ($p < 0.001$). Practitioners were encouraged to use intensive therapy despite this initial setback and work in close collaboration with an opthamologist. Weight gain was also a problem associated with intensive therapy, with patients gaining a mean 4.6 kg over conventional therapy in a five-year period. The incidence of hypoglycemia was three times higher for the intensive group over the conventional group ($p < 0.001$). However, there were no deaths, myocardial infarctions, strokes, or seizures associated with hypoglycemia.

The beneficial effects of intensive therapy far outweigh the adverse effects, and this modality was recommended wherever clinically appropriate. Frequent SMGB testing and patient self-management education was recommended to minimize unwanted sequelae of intensive therapy (Diabetes Control and Complications Trial Research Group, 1993). The DCCT presented unequivocal evidence of the efficacy of glycemic control in preventing the complications of diabetes type 1.

Intensive Therapy Benefits in Type 2 Diabetes

Although the DCCT (1993) results hinted that similar benefits for complications through intensive blood glucose control could be achieved in type 2 diabetes, three studies by the UK Prospective Diabetes Study (UKPDS) Group (1998a, 1998b, 1998c) provided the clinical evidence for decreased risk of diabetic complications resulting from improved glycemic control and "tight" blood pressure control in type 2 diabetes. The UKPDS Group conducted the largest and longest studies of their kind involving type 2 diabetes and results of these published studies provide the basis for many of the ADA

guidelines pertaining to type 2 diabetes (American Diabetes Association, 1999e). Two of the studies involved intensive blood glucose control, one using sulfonylureas or insulin (UKPDS, 1998a), and one using metformin in overweight patients (UKPDS, 1998b). These two studies examined the effects of intensive blood glucose management on risk for complications in type 2 diabetes. The third study (UKPDS, 1998c) involved tight control of blood pressure in type 2 diabetes and the effect it had on risk for microvascular and macrovascular complications.

In a randomized controlled study, the UK Prospective Diabetes Study Group (1998a) followed 3,867 newly diagnosed persons with type 2 diabetes over a median of 10 years, interquartile range (IQR) 7.7 – 12.4, to determine whether pharmacological therapy with sulfonylurea or insulin to reduce blood glucose levels would reduce cardiovascular and microvascular complications. Sample characteristics were a mean age of 53.3 (SD = 8.6) years, 61% were male and 39% were female, 81% were of Caucasian ethnicity, 10% were of Asian-Indian ethnicity, 8% were of Afro-Caribbean ethnicity, 1% other ethnicity, mean BMI was 27.5 (SD = 5.2), and mean HbA1C was 7.08% (SD = 1.51). The intensive therapy group (n = 2729) was treated with nutrition therapy and one or a combination of a sulfonylurea and insulin to attempt to reach a treatment goal of fasting plasma glucose (FPG) < 108 mg/dl (6.0 mmol/L). Conventional therapy, in the control group (n = 1138), consisted of nutrition therapy to reach a goal of FPG < 270 mg/dl (15.0 mmol/L). When patients exceeded FPG of 270 mg/dl (15.0 mmol/L) they were given the same pharmacological therapy as the intensive therapy group. Ultimately, 80% of the conventional group required one or more pharmacological agents.

The UK Prospective Diabetes Study Group (1998b) used a similar design and treatment goals to compare intensive blood glucose control using metformin and nutrition therapy against conventional therapy (nutrition therapy alone) in overweight (greater than 120% ideal body weight) type 2 diabetics (n = 1704). Patients were randomly assigned to either conventional therapy (n = 411), intensive therapy treated with metformin (n = 342), or to an intensive therapy control group treated with sulfonylurea and/or insulin and nutrition therapy (n = 951). Sample characteristics were a mean age of 53.8 (SD = 8) years, 46% were male and 54% were female, 86% were of Caucasian ethnicity, 5% were of Asian-Indian ethnicity, 8% were of Afro-Caribbean ethnicity, 1% were of other ethnicity, mean BMI was 31.4 (SD = 4.6), and mean HbA1C was 7.2% (SD = 4.6).

The UK Prospective Diabetes Study Group (1998c) studied a randomized sample of type 2 diabetics (n = 1148) with concurrent hypertension (defined as systolic blood pressure $\geq$ 160 mm Hg and /or diastolic blood pressure $\geq$ 90 mm Hg). In patients receiving antihypertensive medications, hypertension was defined as systolic blood pressure $\geq$ 150 mm Hg and/or diastolic blood pressure $\geq$ 85 mm Hg. The sample was divided into a "tight control" group (n = 578) with the treatment goal for blood pressure < 150/85 mm Hg, and a "less tight control" group (n = 390) with the blood pressure treatment goal < 180/105. The tight control group characteristics were a mean age of 56.4 (SD 8.1) years, 54% were male, 86% were of white ethnicity, 8% were of Afro-Caribbean ethnicity, 5% were of Asian-Indian ethnicity, 1% were of other ethnicity, mean BMI was 29.8 (SD 5.5), mean HbA1C was 6.9% (SD 1.7), and mean blood pressure was 159/94 mm Hg (SD 20/10). The "less tight" group characteristics were a

mean age of 56.5 (SD 8.1) years, 58% were male, 88.2% were of white ethnicity, 6.4% were of Afro-Caribbean ethnicity, 4.4% were of Asian-Indian ethnicity, 1% were of other ethnicity, mean BMI was 29.3 (SD 5.5), mean HbA1C was 6.8% (SD 1.5), and mean blood pressure was 160/94 mm Hg (SD 18/9). Blood pressures (diastolic phase 5) were measured by a trained nurse using a Copal UA-251 or a Takeda UA-751 electronic auscultatory blood pressure reading machine, or with a Hawksley random zero sphygmomanometer in patients with atrial fibrillation. The tight control group was treated with an angiotensin converting enzyme inhibitor (captopril), and a beta-blocker (atenolol), as the main treatment drugs. The less tight control group was treated with other antihypertensive medications, avoiding the use of beta-blockers and angiotensin converting enzyme inhibitor drugs.

Reduction in microvascular and overall diabetes complications. The UK Prospective Diabetes Study Group (1998a) found a 12% risk reduction (95% CI, 1-21; $p = 0.029$) for any diabetes-related endpoint in the intensive group treated with sulfonylurea and/or insulin over the conventional treatment group. "Any diabetes endpoint" was defined as sudden death, death from hyperglycemia/hypoglycemia, fatal/non-fatal myocardial infarction, renal failure, heart failure, angina, stroke, vitreous hemorrhage of the eye, retinopathy requiring photocoagulation procedure, blindness in one eye, cataract extraction, or amputation of at least one digit. A 25% risk reduction (95% CI, 7 – 40; $p = 0.0099$) in overall microvascular complications was observed in the intensive therapy compared with the conventional therapy group. The UK Prospective Diabetes Study Group (1998b) intensive therapy group treated with metformin had a 32% risk reduction

(95% CI, 13-47; p = 0.0023) over the conventional therapy group for any diabetes-related endpoint. The metformin group also had fewer "any diabetes-related endpoints" (98) than the intensive therapy control group treated with sulfonylurea or insulin (350), indicating reduced risk of diabetes complications for obese persons using metformin (p = 0.0034) over either conventional therapy or sulfonylurea/insulin intensive therapy. The UK Prospective Diabetes Study Group (1998c) found that tight blood pressure control produced a 24% (95% CI, 8-38; p = 0.0046) decrease in risk for all diabetes-related endpoints, and a 37% risk reduction (p = 0.0092) in microvascular disease compared with less-tight control. Tight blood pressure control also demonstrated a 34% decrease in the proportion of patients with deterioration by two steps of retinopathy by a median of 7.5 years (p = 0.004). Risk for deterioration in vision by three lines of the Early Treatment of Diabetic Retinopathy (ETDRS) chart was decreased by 47% (95% CI, 7-70); p = 0.004). Furthermore, the tight control group had a 29% decreased risk (p = 0.009) for microalbuminuria (urine albumin concentration $\geq$ 50 mg/L), with a non-significant 39% decreased risk (p = 0.061) for proteinuria (urine concentration $\geq$ 300 mg/L).

Macrovascular complications and myocardial infarction risk reduction. The UK Prospective Diabetes Study Group (1998a) found a 16% risk reduction (p = 0.052) for myocardial infarction in the intensive therapy group treated with sulfonylurea/insulin. Although statistically insignificant, this was suggestive of benefit for macrovascular complications through glycemic control. The researchers suggested that the 10 years of study were not long enough for macrovascular disease to develop. In contrast, the UK

Prospective Diabetes Study Group (1998b) found a 39% decrease in risk ($p = 0.010$) for myocardial infarction in the metformin intensive therapy group compared with the conventional therapy group. For all macrovascular diseases together (myocardial infarction, stroke, sudden death, angina, and peripheral vascular disease) the metformin intensive therapy group showed a 30% (95% CI, 5-48; $p = 0.02$) decrease in risk over the conventional therapy group. There was no difference between the metformin intensive therapy group and the intensive therapy control treated with sulfonylurea and insulin in risk for macrovascular disease and myocardial infarction. The UK Prospective Diabetes Study Group (1998c) found a non-significant 21% risk reduction in the tight blood pressure control group for myocardial infarction, with a 44% ($p = 0.013$) reduction in risk for fatal/non-fatal stroke over the less-tight blood pressure control group. With all macrovascular diseases combined (myocardial infarction, sudden death, stroke, and peripheral vascular disease) the tight blood pressure control group had a 34% ($p = 0.019$) reduction in risk compared with the less-tight group.

Glycemic control improvement. Over the 10-year study period, HbA1C levels were lowered in the sulfonylurea/insulin intensive therapy group to a median of 7.0% compared with the conventional therapy group 7.9% ($p < 0.0001$). This translates to an 11% reduction in median HbA1C in the intensive therapy group (UK Prospective Diabetes Study Group, 1998a). The UK Prospective Diabetes Study Group (1998b) found HbA1C levels similar between the metformin intensive therapy group and the intensive control group treated with sulfonylurea/insulin. The compared median HbA1C values in the metformin and conventional therapy group were 7.4% and 8.0%,

respectively (no significance values given) over the 10 years of follow-up. In both studies, intensive therapy (drugs plus nutritional therapy) was found to improve HbA1C levels compared with conventional therapy (nutrition therapy alone).

Blood pressure improvement. The UK Prospective Diabetes Study Group (1998c) found a significant reduction in blood pressure over a median follow-up of 8.4 years, to a mean of 144/82 mm Hg in the tight blood pressure control group compared with a mean of 154/87 mm Hg in the less-tight group ($p < 0.0001$). Three or more hypotensive agents were required to reach treatment goals in 29% of the patients in the tight control group. The authors concluded that reducing blood pressure should have a high priority when caring for patients with type 2 diabetes.

Adverse Effects of Intensive Therapy in Type 2 Diabetes

The UK Prospective Diabetes Study Group (1998a) identified adverse effects from intensive therapy with sulfonylurea/insulin as weight gain (mean gain of 2.9 kg, $p < 0.001$) and hypoglycemia (1.0% incidence for those treated with chlorpropamide, 1.4% with glibenclamide, and 1.8% with insulin, $p < 0.0001$). Other than the small fraction of hypoglycemia events there were no significant safety concerns raised by the study that would contraindicate tight glycemic control therapy in type 2 diabetes. The UK Prospective Study Group (1998b) found the proportion of patients with any hypoglycemia episode over the 10-year study period to be lowest in conventional therapy (0.9%), followed by metformin (4.2%), sulfonylureas-chlorpropamide (12.1%) and glibenclamide (17.5%), and insulin (34%). None of the hypoglycemic episodes with metformin were identified as major episodes (requiring intervention by medical

personnel). Weight gain over the 10-year follow-up was similar between intensive metformin therapy and conventional therapy. Both were less than the weight gain for the intensive control group treated with sulfonylurea/insulin (no specific numbers were reported in the study, the finding was illustrated on a graph and reported as above in the text). The authors concluded that metformin could be chosen as a first-line pharmacological therapy to treat obese type 2 diabetes patients.

Summary of the UKPDS and DCCT Findings

Intensive blood glucose control of type 2 diabetes by metformin, sulfonylurea, or insulin therapy significantly decreases the risk for microvascular complications, and somewhat less significantly, for macrovascular disease. Intensive control resulted in weight gain and risk for hypoglycemia, but these were not a contraindication for continued treatment (UK Prospective Diabetes Study Group, 1998a, 1998b). Tight blood pressure control in type 2 diabetes demonstrated decreased risk for both microvascular and macrovascular complications (UK Prospective Diabetes Study Group, 1998c). The DCCT (1996) and UKPDS (1998a, 1998b, 1998c) studies demonstrate the safety and efficacy of tight glycemic and blood pressure control on both types 1 and 2 diabetes. They show that reducing blood glucose and blood pressure levels can produce significant reductions in the incidence and progression of diabetes complications.

Cost Savings from Tight Glycemic Control

One of the concerns of disease management is cost reduction. The Diabetes Control and Complications Trial Research Group (1996) developed a Monte Carlo simulation model and used @RISK: Risk Analysis and Modeling Software Version 1.12 (Pallisade

Corporation, Newfield, NY) computer software to project lifetime benefits and costs of conventional and intensive insulin therapies. Data were collected as part of the DCCT study and it was augmented with data from other clinical trials and epidemiological studies. The model randomly selects an individual from a hypothetical sample of persons with type 1 diabetes and simulates the course of the disease over the patient's projected lifetime using empirical data from the DCCT on disease progression over nine years of conventional and intensive therapies. The process repeats for each of 10,000 individuals in the hypothetical sample until all individuals selected have died.

Costs of various therapies were assigned and total costs were calculated for each treatment group. Types of costs not included were loss of wages from long-term disability and premature death and costs of transportation, lodging, and family care arising from disease. Life-years gained was used as the primary measure of effectiveness. Also tracked were years free from blindness, end-stage renal disease (ESRD), amputation, and complications. Quality-adjusted-life-years (QALY) was a summary measure used to adjust length of life for quality of life.

Benefits of intensive therapy were 7.7 additional years of sight, 5.8 additional years free from ESRD, 5.6 additional years free from amputation, 15.6 additional years free from significant microvascular or neurological complication, and 5.1 years increase in survival. From a healthcare system perspective, intensive therapy costs $28,661 per year of life gained or $19,987 per QALY gained. Laupacis, Feeny, Detsky, and Tugwell (as cited in the Diabetes Control and Complications Research Group, 1996) found that these figures were within a range considered to be cost-effective ratios for other widely

adopted medical treatments in the United States. The Diabetes Control and Complications Trial Research Group (1996) states the costs of conventional therapy were vastly underestimated in the DCCT (1996) study, especially if disability, lost wages, and premature mortality were taken into consideration. An even greater degree of savings through intensive therapy can be expected based on the results of this study.

Clearly, the secondary and tertiary prevention measures of the American Diabetes Association standards of care can make a major impact on reducing costs and improving quality of life. Reeder (1999) states that an assumption of disease management is that the identified population must be currently experiencing variations in treatment and outcomes, and that an optimal way to treat patients exists to decrease that variation, improve quality, and lower costs. If the ADA guidelines are indeed the means to assess and improve quality, and thereby lower costs, then it remains to be shown that a variation in treatment and outcomes exists in our prospective study population for disease management to improve.

Need for Improved Diabetes Care Examined

In a prospective cohort study of risk factors for cardiovascular and cerebrovascular disease in community-dwelling adults $\geq$ 65 years age (n = 5,201, original cohort), Smith et al. (1999) identified 782 subjects as having diabetes through drug inventory, or by fasting blood glucose (FBG) $\geq$ 126 mg/dl. The diabetic subjects were 52% male, 91% white, with average age 73 years. Smith et al. found > 80% of pharmaceutically treated diabetic patients at baseline (n = 386; mean baseline fasting blood glucose 177 mg/dl) were not achieving treatment goals of FBG $\leq$ 120 mg/dl. After seven years of follow-up,

there was no overall change in mean FBG (-4 mg/dl; 95% CI, –14 to 6) in treated patients (n = 196) that survived to follow-up. Less than 30 percent of the pharmaceutically treated patients were achieving recommended levels of control at the seven-year follow-up. At baseline, 396 participants were identified with diabetes by FBG levels $\geq$ 126 mg/dl and these were not currently being treated with antidiabetic agents. Mean FBG of this "untreated group" was 159 mg/dl. After one year, only 16% of the untreated group were being treated with an antidiabetic agent (p = 0.003). At the seven-year follow-up, of the participants that survived and reported for evaluation (n = 244), 56.6% were not on any medication. Change in mean FBG from baseline in the untreated group at the seven-year follow-up was –9 mg/dl (95% CI, –18 to –1). Study data suggested that there was no perceived need on the part of physicians to switch therapies even though patients were not meeting treatment goals. The authors concluded that elderly diabetic patients were not currently meeting ADA treatment goals.

Bernard, Anderson, Cook, and Phillips (1999) surveyed internal medicine residents (n = 145 out of 161 total) at the General Medicine Clinic of Grady Health Systems in Atlanta, Georgia to assess the frequency at which they performed key diabetes quality-of-care indicators based upon ADA guidelines. Residents' characteristics were: 101 males and 44 females, average age 28 years, and consisted of first-year (34%), second-year (36%), and third-year (30%) residents. Using ADA standards, residents reported that they referred diabetic patients for an eye exam (60%), performed lipid testing (50%), and screened for albuminuria (65%) of the time, on an annual basis, when responses should

have been 100 percent for each. Only 52% claimed that they performed foot exams at the recommended frequency.

HbA1C values were examined for 140 of the 210 type 2 diabetic patients seen by residents in the study (Bernard et al., 1999). Fifty-one percent of patients on oral agents and 47% of patients on insulin were not meeting goals for HbA1C (mean sample values not provided by authors). Values for patients not meeting goals were > 8% (goal range; 6.6 - 7.5%). Just 49% of residents surveyed were able to identify the accepted goal range for HbA1C values.

The Diabetes Attitudes Survey for Practitioners developed by Anderson, Donnelly, Gressard, and Dedrick (1989) was used by Bernard et al. (1999) to assess the residents' perceived need for additional training. The survey has a subscale that measures practitioners' attitudes toward their need for special diabetes training. Response options range from 5 (strongly agree) to 1 (strongly disagree). Coefficient alpha (a) was used to determine the reliability of this training subscale. The authors felt that coefficient alpha (a > 0.55) indicated acceptable subscale reliability for this study. Higher scores reflected subjects' endorsement of additional training. Scores on the four training questions responded to by 145 of 161 residents averaged 3.1 ± 0.4, indicating that residents did not perceive that they needed additional training related to diabetes care. Bernard et al. concluded that this study identified a need for programs designed to effectively teach and reinforce diabetes care that meets national standards of care.

These studies show that there exists a variance from accepted standards in patient outcomes and knowledge of practice standards among residents. Implementation of a

disease management program that increases patient and physician awareness of ADA guidelines and assesses compliance with these guidelines will improve quality of care, increase patient and physician satisfaction, reduce complications from diabetes, and reduce the costs of healthcare to society.

Disease Management Interventions in the Literature

Joshi and Bernard (1999) suggested that nurses make reminder phone calls as one means of encouraging patient compliance with follow-up office visits. In a study of 19,523 randomly assigned diabetic patients divided into single reminder and multiple reminder intervention groups for eye examinations Halbert, Leung, Nichol, and Legorreta (1999) found that multiple reminders were more effective than single reminders ($p < 0.023$), but that the effect lost significant value with the third reminder. Considering the costs in time and mailing expense, there appeared to be no benefit in more than two reminders.

Aubert et al. (1998) examined the effect of utilizing a nurse case manager to follow diabetic clients under the direction of a family physician and an endocrinologist as a low-cost method of implementing ADA guidelines into clinical practice. HbA1C levels were examined as a means of evaluating success of the program. Seventeen type1 diabetes patients and 121 type 2 diabetes patients were randomly assigned to either the intervention group (followed by a nurse case manager) or the usual care group (physician-managed without nurse). The intervention group contained 71 patients with a median age of 53 years (IQR 47-61), 17% were type 1 diabetes, 37% were male, and 83% were white. The usual treatment group consisted of 67 patients with a median age of

54 years (IQR 46-60), 8% were type 1 diabetes, 43% were male, and 70% were white. Patients were excluded if they had HbA1C levels less than 7.0 % or medical problems beyond the training of the nurse. The nurse followed established algorithms for medication adjustments and followed ADA guidelines for scheduled lab tests and clinic visits. The nurse also met with the family medicine physician and the endocrinologist at least bi-weekly to review the patients' progress. Patients in the intervention group were referred to a 12-hour diabetes education course that included education by a dietician and an exercise therapist. Patients in the usual care group were given a glucose-testing meter and were encouraged to discuss enrollment in the classes with their primary care provider. Nurse interventions included follow-up calls every two weeks if treated with oral meds, diet, and exercise therapy, and weekly follow-up calls if on insulin.

Hemoglobin A1C values were assessed at baseline and at six months (Aubert et al., 1999). Mean HbA1C for the intervention group at 6 and 12 months was 7.3%, and the mean for the usual care group was 8.3%. The mean HbA1C change in the intervention group was -1.7%, and -0.6% for the usual treatment group. The difference between groups was –1.1% (95% CI, –1.62 to 0.58; $p < 0.001$). Both groups expressed an improved perception of health status, but the patients in the intervention group were twice as likely to report this ($p < 0.02$). The maximum effect in HbA1C improvement was at six months, and was sustained at 12 months. The study shows that a nurse-implemented diabetes management program in collaboration with other healthcare team members can help patients achieve near-normal glycemic control.

Assessment Tools for Measuring Compliance with ADA Standards of Care

Two studies that involved assessment tools for measuring adherence to ADA standards of care were reviewed. Wylie-Rosett, Cypress, and Basch (1992) developed an instrument based upon prevailing standards of care in 1992 called the Diabetes Quality Assurance (DQA) checklist. Weighted point values were attached to each ADA standard of care indicator (based on a risk value attached to that indicator by a panel of seven diabetes experts who reviewed the instrument) for a possible total of 100 points if all standards were met. Data were collected using a specific written protocol that standardized chart review procedures. Inter-rater reliability compared the DQA checklist scores obtained by two reviewers at the same time. Intra-rater reliability compared the DQA checklist scores by the same reviewer at two separate points in time. Inter-rater and intra-rater reliability for the general assessment was established using Pearson correlation coefficients and analysis of variance. Inter-rater reliability estimated a high degree of agreement between two reviewers with "r " values ranging between 0.73 - 0.94. Intra-rater reliability estimated consistency over time of the same rater when "r " values ranged between 0.60 - 0.97. Inter-rater reliability assessed by the authors for the DQA checklist in this study was r = 0.94 (95% CI 0.86-0.97) on Time One, and r = 0.91 (95% CI 0.81-0.96) on Time Two. Intra-rater reliability for the DQA checklist in this study was found to be r = 0.84 (95% CI 0.65-0.92) on Time One, and r = 0.75 (95% CI 0.49-0.84) on Time Two. The scores indicate that the DQA checklist is reliable for achieving the same results when used by the same reviewer at different points in time, or by two different reviewers at the same time. No parameters were provided in the study as to what a

specific total point value signified in relative adherence to ADA guidelines or quality of care. The more heavily weighted indicators were considered riskier behaviors for the patient. The tool would appear to be a good assessment instrument of the patient's relative risk, but does not directly measure adherence to ADA guidelines.

Casey and Egede (1999) developed a disease management instrument to improve physician compliance with 1995 ADA standards of care. The tool consisted of a preprinted Diabetes Visit Progress Note that addressed 12 standards of diabetes care for physicians to assess. Standards included were diet, weight, medications, SMBG testing, diabetes-related counseling, vital signs, eye exam, foot exam, review previous lab tests, review today's lab tests, consultations, and follow-up exams. Chart reviews prior to implementation of the tool and 18 months following its use were done on 41 type 2 diabetes patients. In this retrospective/prospective follow-up study design, the Wilcoxon Signed Ranks Test was used to assess physician compliance. Visit scores improved in 11 of 12 categories ($p < 0.05$). Validity and reliability measures used in the study were not discussed by the authors.

Summary

Disease management is a new and emerging way to deliver care. Nurse have the potential to play a major role in the development and implementation of disease management programs. However, studies are limited regarding its effectiveness in saving money for the healthcare system and managing long-term health risks in chronic diseases such as diabetes. This study investigated whether the disease management model of care will improve patient outcomes. Improving glycemic control and adherence to ADA

standards of care through disease management appears to be effective based upon the literature reviewed. Nurses can use the information gained from this study to enhance their role as leaders in improving the quality of patient care. Nurses, using data from the study to evaluate concepts found in the literature review, can be instrumental in designing disease management programs that will decrease complications in their diabetes clientele.

CHAPTER III: METHODS

Introduction

This chapter provides information about the study design, setting, sample, and the methods proposed for gathering and analyzing data. The means for protecting human rights and confidentiality are described, together with the institutional review boards approval of the study before it was implemented. A description of the process used to establish reliability and content validity of the instrument is also included.

Research Design

There are a limited numbers of studies on diabetes and disease management, and numerous factors may impact upon glycemic control and adherence to treatment guidelines. This study employed a quasi-experimental pre/post intervention design to compare any differences in diabetes treatment efficacy between traditional primary care and disease management care in an Air Force diabetic population. The population was managed under traditional primary care for its diabetes, and was then subsequently entered into a disease management program of a midwestern military facility. This researcher retrospectively gathered data through patient chart reviews at the respective clinics using a specific instrument (see Appendix B) with written criteria for how data were to be recorded.

Sample and Setting

The setting for the study (described above) was chosen because the researcher is an Air Force nurse with an interest in diabetes. Air Force Instruction AFI 144-102, 1 July 98 (see Appendix C) established the directive for Air Force medical treatment facilities to

implement clinical practice guidelines and use of critical pathways for the management of high cost, high risk, and problem prone diseases such as diabetes. The family medicine clinic at this base implemented a diabetes disease management program in October 1998.

An attempt was made to review charts of all subjects in the disease management program. Casey and Egede (1999) were able to get statistically significant results ($p < 0.05$) by studying a sample size of 41 type 2 diabetes patients while researching the effects of a disease management tool on adherence to ADA standards of care. Aubert et al. (1998) achieved statistically significant results ($p < 0.001$) by studying a randomized controlled sample of 138 mixed typel and type 2 diabetes patients in a disease management program. Aubert et al. assessed glycemic control by comparing mean change in hemoglobin A1C values. By including the whole population of eligible subjects in the present study sample, there was a greater likelihood of achieving a .05 significance level, thus avoiding a Type I error. The present study sample ($n = 28$) included all patient records available for review but was less than that used by other researchers.

Sample Inclusion Criteria

All subjects with diagnosed type 1 and type 2 diabetes who had been in traditional primary care for at least one year prior to entering the disease management program were included in the sample. Subjects were also required to be in disease management for at least 12 months at the time of data collection.

Sample Exclusion Criteria

For the glycemic control variable, new onset type 1 diabetes subjects whose diagnosis was within 6 months of the 12-month period of chart review in the traditional primary care were excluded from collection of HbA1C levels. Newly diagnosed type 1 diabetics often go through a "honeymoon phase" from one to four months following diagnosis where their blood glucose levels improve dramatically, only to go out of control when the pancreas fails following this honeymoon phase (Olson, 1988). Results included from this period would skew the results away from the effect caused by the research variables.

For the glycemic control variable, subjects with newly diagnosed type 2 diabetes were required to be in traditional primary care for three months prior to the study period to allow HbA1C values to reflect the interventions implemented by the traditional primary care provider(s) and not that of their glycemic control prior to diagnosis (see operational definition of HbA1C in Chapter I). Out of 72 diabetes patients identified at the study facility, 24 patients were excluded because they were not in traditional care 12 months prior to entering the disease management program, 16 patients were excluded because the charts were not available for review, and 4 patients were only receiving part-time care at the facility and received their diabetes care elsewhere. The final sample size was 28 patients that met all inclusion criteria.

Measurement Methods

The independent variable in this study was the implementation of a disease management program with the study sample. The dependent variables were adherence to

American Diabetes Association guidelines, and glycemic control (as measured by hemoglobin A1C levels within the sample, measured before and after disease management).

The "adherence to American Diabetes Association guidelines" data are nominal data ("standard met", or "standard not met"), and the hemoglobin A1C values are scale data in the form of percentages of glycated hemoglobin calculated by the facility's laboratory. The study instrument, Adherence to ADA Guidelines Assessment Checklist (see Appendix B), was completed for each subject during the chart review. The standards of care items were marked as "Y" for standard met, or "N" for standard not met, at appropriate intervals for each standard while in traditional and disease management care. ADA standards of care selected for inclusion on the instrument were derived from the American Diabetes Association: Clinical Practice Recommendations 2000 (American Diabetes Association, 2000). Selections of specific standards of care for assessment were based upon the literature review, and review of the proposal for the National Quality Management Special Study: The 1999 Review Plan-Diabetes (Department of Defense/Veterans Administration, 1999). Using ADA standards that are being studied in the proposed National Quality Management Special Study will allow for potential comparison of future findings between that study and the present study. Similar findings will strengthen the significance and validity of these results.

Three standards of care on the Adherence to ADA Guidelines Checklist- tobacco and alcohol assessment each visit, annual flu shot recommendation, and pneumococcal immunization recommendation, were not listed in the Position Statement: Standards of

Medical Care for Patients With Diabetes Mellitus (American Diabetes Association, 1999g). They were included because influenza immunization (Centers for Disease Control and Prevention, 1997a), pneumococcal immunization (Centers for Disease Control and prevention, 1997b), and tobacco and alcohol assessment (National Cholesterol Education Program, 1993) were accepted preventive health measures for diabetes patients at the time of the study. They were subsequently included in the American Diabetes Association standards of care for 2000 (American Diabetes Association, 2000).

The HbA1C values were recorded at baseline, 6 months, and 12 months for the period each subject was in traditional care and in disease management care. Values were recorded on the Adherence to ADA Guidelines Assessment Checklist (see Appendix B). Any missing values at the measurement intervals were noted and adjusted for in the statistical analysis.

Demographic data, including age, sex, ethnicity, type 1 or type 2 diabetes, type of drug treatment, and number of years with diabetes were collected in order to describe the sample, and to be able to compare any impact these variables may have in the present study compared to other similar studies.

Instrument Reliability

Reliability testing of a study instrument is necessary to establish how consistent the instrument measures an observation between raters, and with the same rater over time. Reliability testing with an instrument needs to be accomplished with each new setting and sample for which the instrument is used (Burns & Grove, 1997). Inter-rater and intra-

rater reliability of the Adherence to ADA Guidelines Assessment Checklist (see Appendix B) were established by using the method described by Wylie-Rosett et al. (1992) with some changes. The Wylie-Rosette study used a convenience sample of twenty-three medical charts that were simultaneously reviewed and scored by two reviewers using the study instrument. The same two reviewers reviewed the same charts five to seven weeks later. Due to time and manning restraints, this researcher reviewed 10 charts at the beginning and end of the week for intra-rater reliability. A second nurse was recruited for inter-rater reliability testing of the study instrument. This nurse was instructed on the theoretical aspects and purpose of the study, familiarized with the study instrument, and given a written set of instructions on what to accept as a positive or negative judgment on each adherence to standard of care indicator on the instrument. The second nurse then reviewed the same 10 charts as the researcher at the end of the data collection week. This procedure and number of charts is consistent with guidelines set forth by Washington and Moss (1988) for establishing inter-rater reliability of a study instrument in research.

Pearson correlation coefficients and kappa analysis were used to assess consistency in mean scores between raters, and scoring stability of the same rater(s) over time.

A high degree of stability over time and reliability between raters was found while using the study instrument in this study. Burns and Grove (1997) suggested as an initial procedure, to divide the number of rater agreements by the total number of possible agreements. A reliability coefficient of 1.0 equals perfect agreement. The authors indicated that a reliability of .80 is considered the lowest acceptable coefficient for a

well-developed research tool, while a coefficient of .70 is acceptable for newly developed instruments. In this study, the scale data had total agreement in 180/180 possible observations in both intra-rater and inter-rater reliability for a 1.0 correlation. For intra-rater reliability, there was agreement in 518/520 possible observations of nominal data for a crude correlation of .99. For inter-rater reliability, there was agreement in 479/520 possible observations of nominal data for a crude correlation of .92. The initial analysis suggested that the instrument had a high degree of consistency between raters, and the same rater over time.

Carletta (1996) indicated that researchers generally consider a kappa coefficient (K) greater than .80 as good reliability in study instruments, with $.67 < K < .80$ indicating only moderate agreement. Tables D1 and D2 in Appendix D summarize actual Pearson correlation coefficients and kappa analysis results for each study item. There was perfect correlation ($r = 1.0$) of Pearson's coefficients in the scale data items for intra-rater and inter-rater reliability. Intra-rater reliability of nominal data (.60 – 1.0) was greater than inter-rater reliability (.20 – 1.0). Kappa analysis of nominal data for intra-rater reliability was $K = 1.0$ ($p = .002$) on 50/52 items scored with 2 items $K = .60$ and $K = .72$. Kappa analysis for inter-rater reliability was $K = 1.0$ ($p = .002$) on 35/52 items scored, with moderate agreement ($.60 < K < .80$) on 7/52 items, and kappa ranged .20 to .58. on the remaining 10/52 items.

Instrument Content Validity

Content validity is a determination of the content representativeness of the items of a study instrument using a two-stage judgment process (Lynn, 1986). First, the individual

items on the instrument are rated by experts in the field of study for content validity on a scale of 1 to 4 (1 = not valid, 4 = very valid). Finally, the entire instrument is rated as to its content validity as a whole using the same scale. A minimum of three experts should be used, and all items must be rated 3 or 4 by the raters when using five or fewer experts in order to establish content validity at the .05 level of significance. The actual content validity index (CVI) is expressed as a ratio of the items rated 3 or 4, divided by the total number of items. Although a CVI of .80 is commonly accepted in research, this study strived for a CVI of 1.0 as advocated by Lynn in order to assure statistically significant content validity of the instrument.

Content validity for the Adherence to ADA Guidelines Assessment Checklist (see Appendix B) used in this study was assessed by presenting the study instrument to four experts selected for their clinical expertise in diabetes care. Initially, the instrument was presented to the Department of Defense (DoD) Champion for the Diabetes Guideline Project. Items 13 and 14 were re-worded based on that review, and the instrument was subsequently rated an overall 4. Three revised instruments were then sent out. Two were evaluated by certified diabetes educators at Joslin Diabetes Center, Boston, MA, and one by an internal medicine physician at Altru Health System Diabetes Center, Grand Forks, ND. Included for each evaluator were the study instrument, an evaluation form, a copy of the American Diabetes Association: Clinical Practice Recommendations 2000, and instructions for completing the form (see Appendix E).

After the changes were made to items 13 and 14, all evaluators rated the individual scale items 3 or 4, with one exception. Three experts rated item 15 (baseline EKG) as a 4,

but one rated it as a 2. The literature strongly supports the correlation between diabetes and coronary heart disease. A baseline EKG for adult patients is an important element of a cardiac evaluation and serves as a document for comparison with any future EKG abnormalities that may arise. It is recommended as a component of the initial diabetes visit (American Diabetes Association, 1999g). Because the ADA guidelines specifically recommend a baseline EKG for all adult patients, and because 3 out of 4 of the experts rated this item as a 4, item 15 was left on the instrument. The final instrument CVI was .95.

Protection of Human Rights

A copy of the study proposal was submitted to the Institutional Review Board (IRB) at the Uniformed Services University of the Health Sciences, Bethesda, MD and written permission to conduct the study was obtained. Mail correspondence with the Chief of Healthcare Integration and Disease Management at the study facility indicated that approval from the IRB at USUHS sufficed for conducting research at the institution (see Appendix F).

The following measures were taken to protect the rights of the patients whose medical records were reviewed, and the rights of the healthcare providers who have provided their care. Access to the master list containing names and identifying information was solely limited to the researcher. Once the data collection was completed at the facility, the master list was destroyed. Charts were not removed from the facility setting by the researcher. Patient information from the records other than that specific to the study was kept confidential and not discussed with anyone. Data from the chart

reviews were compiled and presented as characteristics of the population sample. Results were not associated with individual subjects or providers.

CHAPTER IV: STUDY FINDINGS

Introduction

This chapter discusses the research findings and the results of statistical testing. A demographic description of the 28 patients in the study sample is presented and compared to the total diabetes population at the study site. Data are reported on glycemic control and adherence to 18 American Diabetes Association standards of care during 12 months of traditional care preceding implementation of a diabetes disease management at the facility, and during 12 months following implementation of the program.

Characteristics of the Study Sample

Provider Staff and Continuity of Care

An attempt was made to assess the level of attrition of subjects and healthcare providers in the sample due to military transfers or other causes. During the traditional care period there were eight providers delivering diabetes care, and six to eight during the disease management period. Two physicians left the military during the course of the study and were replaced by two new physicians. One nurse practitioner was transferred to another facility, and one physician assistant was reassigned to another clinic midway through the disease management period and were not replaced. No data could be obtained on how many patients left the facility during the study period. However, the reduction in staff maintained a 1:1500 provider to beneficiary ratio.

Table 1

Demographic Characteristics of Sample and Population by Treatment Modality

Characteristic	Traditional Care Value	Traditional Care Range	Disease Management Value	Disease Management Range
Study Sample (n = 28)				
Mean age, y	45	16 – 62	46	17 – 63
Male patients, %	39.3		39.3	
Female patients, %	60.7		60.7	
Mean duration of diabetes, y	7	2 - 19	8	3 - 20
Mean Body Mass Index, kg/m2	31.3	20.1 - 44.7	31.0	21.0 - 46.1
Patients with type 1 diabetes, %	21.4		21.4	
Patients with type 2 diabetes, %	78.6		78.6	
Caucasian, %	82.1		82.1	
African American, %	7.1		7.1	
Asian, %	3.6		3.6	
Hispanic, %	7.1		7.1	
Duty status				
Active duty, %	10.7		10.7	
Retiree, %	28.6		28.6	
Dependent, %	60.7		60.7	
Total Population (N = 72)				
Mean age, y	46.3	16 – 64	47.3	17 – 65
Male, %	51.4		51.4	
Female, %	48.6		48.6	
Patients with type 1 diabetes, %	13.9		13.9	
Patients with type 2 diabetes, %	86.1		86.1	
Duty Status				
Active Duty, %	11.1		11.1	
Retiree, %	37.5		37.5	
Dependent, %	51.4		51.4	

The Sample Compared to the Study Population

Table 1 summarizes the demographic characteristics of the sample and how it compares to the population being studied. The table shows the sample (n = 28) to be middle-aged, mostly type 2 diabetes patients, of mixed ethnicity although largely Caucasian, moderately obese (BMI > 27), with mean duration of disease less than 10 years. The sample was very similar to the study population (N = 72), with 12.1 % fewer males in the sample than in the total population. Both the sample and total population contained similar proportions of active duty, dependents, and retiree personnel. Data on the ethnicity, BMI, and duration of diabetes were unavailable on the total population and are not presented in Table 1.

Data Analysis

Effects of Disease Management on Glycemic Control

Glycemic control in this study was assessed by comparing mean change in hemoglobin A1C (HbA1C) values measured at baseline and 12 months for each of traditional care and disease management periods. The significance of these scale data were analyzed in SPSS statistical software using a paired t-test. The American Diabetes Association (ADA, 1999g) recommends goals for glycemic control to be HbA1C < 7% with action suggested for HbA1C > 8%. Subjects were chosen that had complete HbA1C data for baseline and endpoint of both study periods (n = 17). Table 2 shows the data for these subjects.

Table 2

Mean Change of HbA1C Values by Treatment Group (n = 17)

Variable	Mean Change in Traditional Care	SD	Mean Change in Disease Mgmt	SD	Difference (95% CI)
HbA1c value, %	-0.4***	1.05	-0.1*	0.84	-0.3** (-1.06 to 0.46)

Note. Two-tailed test. ***p = .12. *p = .57. **p = .41. SD = Standard Deviation.

On the surface it appears that there was a 0.3% greater decrease in HbA1C during the traditional care period, albeit not statistically significant. Table 3 compares the actual group means during the two study periods.

Table 3

Mean HbA1C Values Compared in Traditional Care and Disease Management Care (n = 17)

Variable	Baseline Visit	SD	Annual Visit	SD
Mean HbA1C in Traditional Care	8.1	1.39	7.7	0.95
Mean HbA1C in Disease Management	7.6	.95	7.5	1.11

Note. SD = Standard Deviation.

Assuming that the providers were following American Diabetes Association guidelines (ADA, 1999g), no action was indicated until HbA1C values are above 8%. The mean HbA1C values for both traditional care and disease management care fall

closely within the 7%-8% range, indicating sample maturity for both groups. Therefore, a significant change in HbA1C values would not be anticipated since providers would not be taking any actions to change those HbA1C values $\leq$ 8%. The fact that the mean baseline and endpoint HbA1C values for disease management remained nearly the same (7.6% and 7.5%, respectively) would seem to indicate that disease management is at least at a minimum, effective in maintaining desirable glycemic control. Recommendations for how to better assess the effectiveness of Disease Management in achieving glycemic control will be discussed in Chapter V.

Effects of Disease Management on Adherence to ADA Guidelines

ADA guidelines seek to prevent the complications associated with diabetes through implementing preventive measures aimed at detecting early disease or deterring its onset. These preventive measures, or standards of care, are used as quality of care indicators in the CQI mechanisms of disease management discussed in Chapter I. This study examined adherence to 18 ADA standards of care (in this study semiannual and annual diabetes visits, and semiannual and annual HbA1C checks were counted as two standards and not four) for 12 months pre/post implementation of a disease management program. Three of these standards, tobacco and alcohol assessment each visit, annual flu vaccination recommendation, and one-time pneumococcal vaccination recommendation, were not listed in the ADA Clinical Practice Recommendations as standards of care until year 2000 and therefore not in effect during the entire study period. However, they were included in the study because they were accepted preventive care measures during the study period (see Measurement methods, Chapter III). Significance of this nominal data

was analyzed in SPSS statistical software using the McNemar statistical test. For each individual ADA standard of care, the mean percentage of the standard met in traditional care was plotted against the mean percentage of the standard met in disease management care and are presented in Table 4 and in Figures 1 and 2.

Table 4 lists the mean percent adherence to each ADA standard of care pre/post disease management. There was an increase in adherence to all ADA standards examined during the disease management period. Of the 15 standards that were in effect during the entire study period, increases in adherence in disease management over traditional care ranged from 10.7% to 42.8%, mean increase 21.9%. Of the three standards that were not in effect the entire study period, increases in adherence during the disease management period ranged from 7.2% to 33.9%.

Table 4

Mean Percent Adherence to ADA Standards Pre/Post Disease Management

Standard of Care	Traditional Care Mean % Adherence	Disease Management Mean % Adherence	p value	Diff %
Semiannual visits	78.6	92.9	.22	14.3
Annual visits	82.1	96.4	.22	14.3
Wt check each visit	78.6	89.3	.18	10.7
BP check each visit	80.4	91.1	.18	10.7

(table continues)

Table 4 (continued)

Mean Percent Adherence to ADA Standards Pre/Post Disease Management

Standard of Care	Traditional Care Mean % Adherence	Disease Management Mean % Adherence	p value	Diff %
SMBG addressed each visit	73.2	83.9	.18	10.7
Nutritional assessment each visit	**39.3**	**64.3**	**.009**	**25.0**
Exercise addressed each visit	**41.1**	**67.9**	**.006**	**26.8**
Tobacco and alcohol assessment*	**12.5**	**46.4**	**< .001**	**33.9**
Self management assessed annual	57.1	82.1	.09	25.0
Comprehensive annual foot exam	**53.6**	**92.9**	**.001**	**39.3**
Annual microalbuminuria screen	**64.3**	**96.4**	**.004**	**32.1**
Annual lipid screen	**67.9**	**96.4**	**.02**	**28.5**
Annual retina exam	75.0	92.9	.13	17.9
Semiannual HgbA1C	75.0	92.9	.13	17.9
Annual HgbA1C	78.6	89.3	.51	10.7
Comprehensive diabetes education	**57.1**	**85.7**	**.008**	**28.6**
Individualized nutrition recommendation	64.3	82.1	.06	17.8
Annual flu vaccination recommended*	3.6	17.9	.13	14.3
Pneumococcal vaccine recommended*	0.7	17.9	.50	7.2
Baseline EKG	**53.6**	**96.4**	**<. 001**	**42.8**

Note. Significant values are highlighted in bold in bold. Asterisk (*) indicates new ADA standard of care added in year 2000.

Increases in adherence to ADA standards achieved both clinical and statistical significance in 8 of 15 standards of care studied. Of these, adherence to nutrition assessed each visit increased 25.0% ($p = .009$), exercise addressed each visit increased 26.8% ($p = .006$), tobacco and alcohol assessed each visit increased 33.9% ($p < .001$), comprehensive annual foot exams increased 39.3% ($p = .001$), annual urine microalbumin screening increased 32.1% ($p = .004$), annual lipid screening increased 28.5% ($p = .02$), comprehensive diabetes education increased 28.6% ($p = .008$), and patients with baseline EKGs increased 42.8% ($p < .001$).

Although not achieving statistical significance, the remaining indicators showed increases in adherence of 7.2% to 25.0%, with a mean of 14.3%. Figure 1gives a bar graph representation of the statistically significant adherence to ADA guidelines data during the traditional care versus the disease management period of this study. Figure 2 presents the rest of the adherence data that did not achieve statistical significance in this sample. Viewing the graphs in Figures 1 and 2 presents some insight about the study results. First, because the tobacco and alcohol assessment, flu shot, and pneumococcal vaccination recommendations weren't ADA standards of care during the study period, it would not be expected that these items would have much compliance. The results on the graph bear out this expectation. Secondly, statistically significant increases in adherence would be more likely to be detected where there is room for improvement as opposed to quality indicators that are closer to 100% compliance. This is also evident in the bar graphs. The pre-disease management, or traditional care quality indicators, in Figure 1 (statistically significant values) fall mostly between the 40th percentile and the 70th

percentile, whereas they fall mostly between the 50th and 80th percentiles in Figure 2 (the non-statistically significant values).

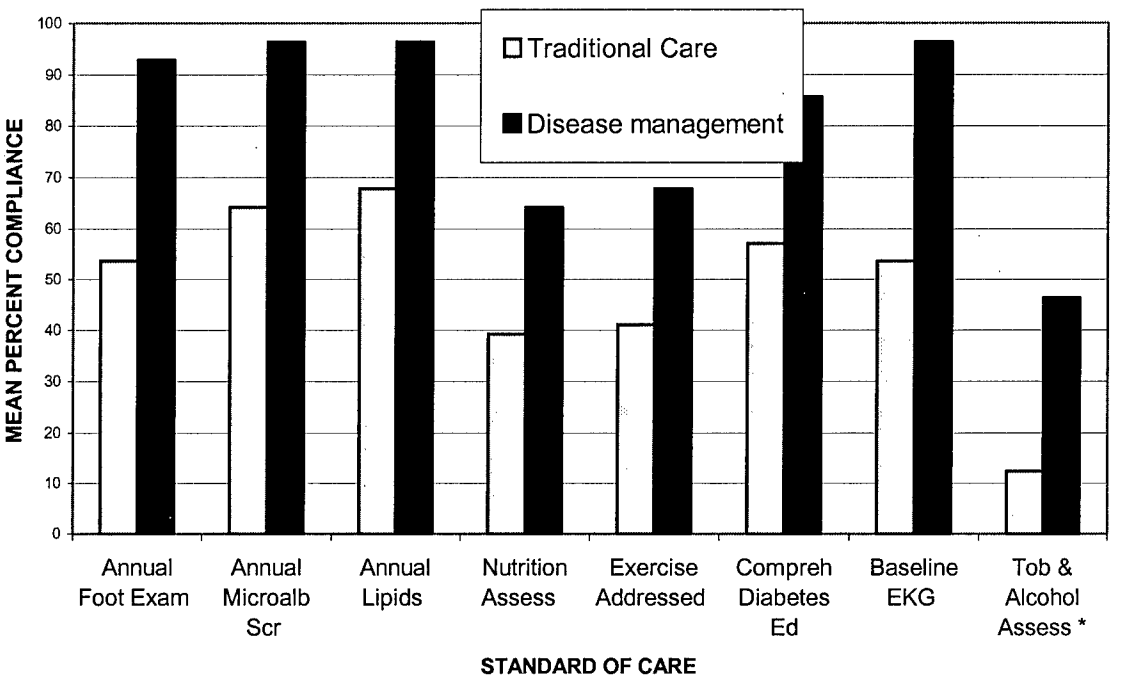


Figure 1.

Statistically Significant Adherence to ADA Standards: Pre/Post Disease Management. Exact significance of each standard is listed in Table 4. Asterisk (*) denotes new ADA standard of care added in year 2000.

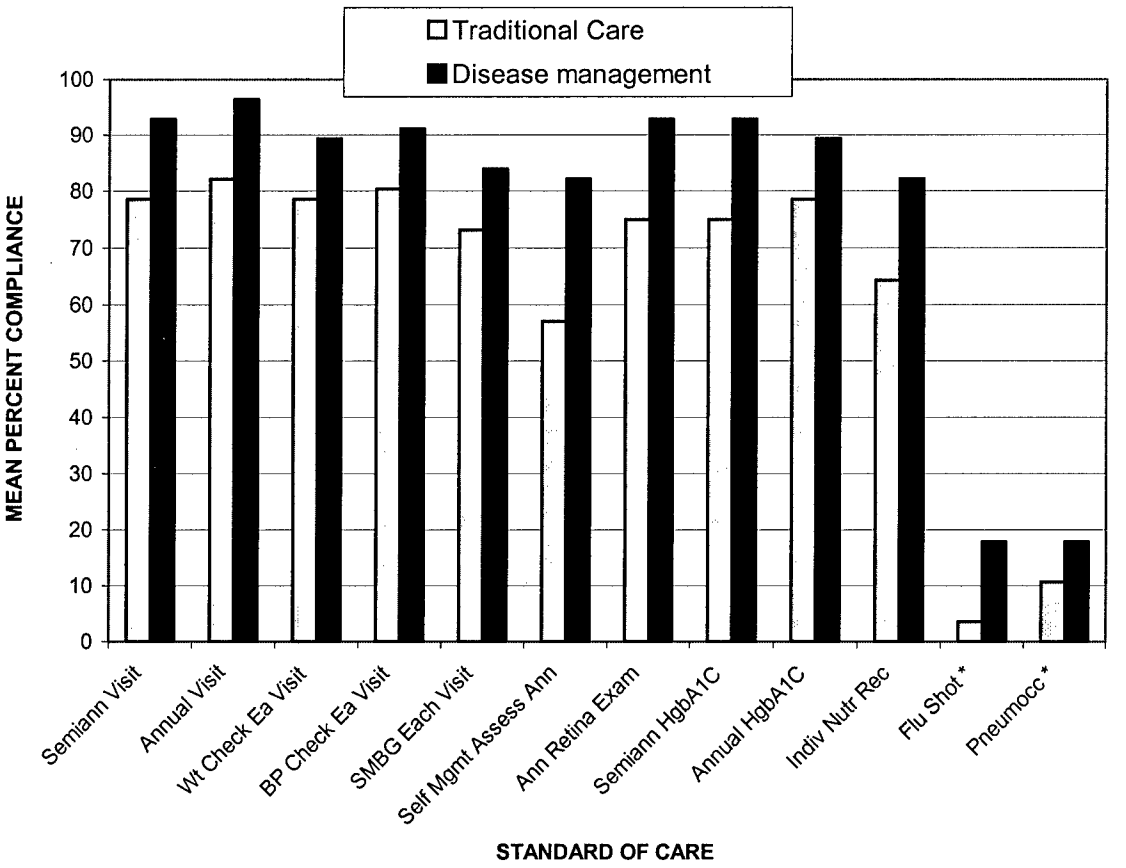


Figure 2.

Non-statistically Significant Adherence to ADA Standards: Pre/Post Disease Management. Asterisk (*) denotes new ADA standard of care added in year 2000.

CHAPTER V: CONCLUSIONS AND RECOMMENDATIONS

Introduction

The purpose of this study was to compare the effectiveness of the disease management model to the traditional primary care model of patient care in achieving glycemic control and adherence to American Diabetes Association (ADA) standards of care in a military outpatient clinic setting. This chapter will discuss the sample size and selection and its effect on the findings of the study, how effective disease management was at achieving glycemic control and adherence to ADA standards, and how well the methodology worked in attaining study results. The study instrument will be discussed and suggestions made for future use by researchers. Some disease management tools that were in use at the study facility will be discussed in relation to the literature review. Finally, the importance of the study results to nursing will be discussed and how nurses may be utilized to implement disease management programs.

Discussion of the Sample

Sample Size and Nonrandomization

Sample size may have been too small to present sufficient statistical power to detect a difference in all outcomes within the group. The presence of a large proportion of normal HbA1C levels in the traditional care (pre-intervention) group may have made any real improvements in HbA1C by the disease management group (post-intervention) appear statistically insignificant. The same could be true regarding adherence to some of the ADA guidelines.

This study compared traditional primary care to disease management care using the study group pre-intervention as the model for traditional primary care, and the same group post-intervention as the model for disease management. Because there was not a concurrent cohort of randomly selected non-intervention individuals as the control group (the whole diabetes population of one military facility was enrolled in disease management), the results will be somewhat less generalizable to all diabetic practices. Further studies could use information gained from this study to devise a controlled study to enhance generalizibility of the findings.

The sample and glycemic control. Because there was a chance for a small effect size in HbA1C levels (the patients were fairly well controlled before entering disease management), a larger sample size was desirable to prevent the possibility of a Type II error. The sample proved too small to detect significant differences in glycemic control between traditional care and disease management care even though there was a small apparent change. The pre/post design of this study did not lend itself to assessment of glycemic control in this sample. The mean duration of disease in the traditional care period was 7 years (range 2 – 19 years). The mean HbA1C at baseline for the traditional care period was 8.1%, and 7.6% for the disease management period. According to ADA (1999) guidelines, providers aren't obligated to take corrective action until patient HbA1C values are greater than 8%. The sample was too mature with respect to glycemic control to detect significant differences in improved control. Future studies about glycemic control between different interventions should attempt to study a larger sample, and use a randomized controlled design. Additionally, the sample should exclude

individuals that are controlled to HbA1C levels $\leq 8\%$ since this is the cutoff where the patient or provider would take corrective action. This would enable the researcher to detect significant differences in HgbA1C levels and eliminate the effect of sample maturation due to patients already being in glycemic control when starting disease management.

The sample and adherence to ADA standards. The pre/post design worked well for assessing adherence to ADA standards in this sample. Significant adherence values were attained for 8 of 18 standards of care studied. The sample size appeared to be a factor in attaining significance for the remaining 10 standards. While these remaining values were clinically significant with a mean increase of 14.3% (range 7.2% - 25.0%) in adherence during disease management, they lacked sufficient power to attain statistical significance. Sample maturity may have also been a factor. While comparing the traditional care columns in Figures 1 and 2, the columns in Figure 2 (non-statistically significant adherence data) are on the whole much closer to 100% than the ones in Figure 1 (statistically significant adherence data). It appears that statistical significance was easier to attain where there was greater room for improvement. Recommendations for future studies would be to strive for a large enough sample size to ensure statistically significant results in the environment of sample maturity.

The Sample and the General Population

As discussed in Chapter II, military and civilian diabetes populations are similar in many respects. The percent of diabetes patients (N = 72) of the approximately 15,000 beneficiaries at the facility is about 0.48%, much less than the 5.9% found in the general

civilian population. A partial explanation is that the military population is younger than the general civilian population and must meet standards for weight and fitness in order to remain in the military, thereby eliminating many potential type 2 diabetics. A number of other diabetes patients are automatically eliminated from the system by becoming Medicare eligible at age 65 and therefore being disqualified from regular care at military facilities. The proportion of type 1 diabetes patients in the study population (13.9%) was also similar to the 5%-10% of type 1 diabetes individuals in the civilian diabetes population. Therefore, cautious generalization of findings from this study might be inferred to civilian populations as well as to other military diabetes populations. Effects such as sample maturation, historical events, facility staffing, and resource availability will again necessitate care in making any generalizations to other populations. Due to the retrospective nature of the study, the subjects and the staff at the study facility had no way of knowing that they were going to be studied. This helped eliminate some of the threats to the internal and external validity of this study.

The Effectiveness of Disease Management

Glycemic Control

Due to design flaws and sample characteristics discussed above, this study was unable to determine the effectiveness of disease management over traditional care in achieving glycemic control. There was no statistically significant difference in change of mean HbA1C values between traditional care and disease management care during the study. What can be said regarding glycemic control, is that it appears disease management is at least as effective as traditional care in maintaining HbA1C levels

within the 7% - 8% range. Further studies need to be done using a randomized controlled design and patients that aren't already controlled to the HbA1C $\leq$ 8% level.

Adherence to ADA Guidelines

Disease management care appeared to be very effective at increasing adherence to American Diabetes Association standards of care compared to traditional primary care. Clinically and statistically significant increases in adherence of 25.0% - 42.8% were achieved in 8 of 18 ADA standards of care despite the small sample size ($n = 28$). The remaining non-statistically significant adherence values showed clinically significant increases of 7.2% - 25%. These are highly suggestive of the value of disease management in achieving improved adherence to ADA standards in light of the small study sample. Additional studies need to be done using a larger sample to further document the value of disease management in improving provider compliance with prevailing standards of care. Based on the findings of this study, a well-designed disease management program can improve diabetes care through increased adherence to ADA guidelines.

Disease Management Tools Used at the Study Facility

Overprinted progress notes. Casey and Egede (1999) studied the use of an overprinted progress note addressing 12 ADA standards of care and found improved compliance by providers in 11 of 12 standards ($p < .05$). One of the disease management tools used by the present study facility was an overprinted progress note addressing 13 of the 18 ADA standards assessed in this study. The standards not on the overprinted progress note include self-management skills assessment, influenza vaccination, pneumococcal vaccination, comprehensive diabetes education, and individualized

nutrition recommendation. A copy of the overprint is in Appendix G. The improved adherence to ADA standards noted in all 18 standards of care in this study is consistent with the findings of Casey and Egede. This tool may have been an important factor in achieving improved compliance at this facility. Further studies should be done to further evaluate the effectiveness of overprinted progress notes in achieving improved compliance to prevailing standards of care in a disease management program.

Staff utilization and record flagging. The study facility utilized the clinic nursing, technical, and clerical staff to ensure the success of the disease management program. When a diabetes patient came in for an appointment the unit clerk was asked to alert the technicians and nurses that the patient was in the disease management program. In order to facilitate this process, a colored half-sheet of paper was placed on the inside cover of the patient record identifying the patient as a member of the disease management program. This also required educating patients so that they didn't become alarmed at the flag. Patients were sent letters and notified by telephone regarding the implementation of the disease management program and its benefits and responsibilities for the patient and his/her healthcare providers.

When the unit clerk saw the flagged chart, they alerted the technician staff so that the technicians could ensure that weight and blood pressure was performed for the appointment, and then direct the patient to the clinic team nurse. The team nurse performed the annual foot exam, if needed, and reviewed the record for any required lab studies. The nurse interviewed the patient to assess any self-management needs and possible referrals to nutrition, ophthalmology, podiatry, or the Health and Wellness

Center. The nurse wrote a pertinent note documenting any needed lab studies or referrals, and then the patient was directed to the provider for their examination. The staff reported that flagging the charts greatly reduced the number of patients that bypassed the process and went directly to the provider without being prepared by the technicians and nurses. Studies could be done evaluating the efficacy of flagging charts in improving disease management processes.

Provider support and education. In the current environment of healthcare utilization with 15-minute provider appointments being the clinical norm, physicians are often resistant to programs that require changes in their established way of practice. Time to learn a new way of doing business is at a premium. Joshi and Bernard (1999) acknowledged this obstacle to instituting disease management at the University of Pennsylvania Health System (UPHS) and offered suggestions to overcome this problem. They advocated intensive effort and energy being focused on effective strategies to gain clinician buy-in to achieve program compliance.

An influential thought leader should be appointed as the program champion. This champion would be instrumental in leading the clinical staff through necessary changes. At the study facility, a senior nurse was appointed as the Chief of Disease Management. The chief then appointed champions for each of four disease management programs to be instituted at the facility. The champion for the diabetes disease management program formed a team to develop clinical guidelines and the overprinted diabetes progress note. Staff meetings were held to educate clinic staff on the disease management process and its benefits for diabetes patients and staff, to gain buy-in for use of the clinical guidelines,

and to foster support for the disease management program. The results of this study show that provider adherence to ADA guidelines improved after implementing a disease management program at the facility. Studies need to be done to determine which measures to achieve clinician buy-in to disease management programs are the most efficacious and cost-effective.

The Adherence to ADA Guidelines Assessment Checklist

The study instrument, the Adherence to ADA Guidelines Checklist (see Appendix B), was developed by this researcher for the present study. The instrument was found to be a reliable measure for adherence to ADA standards of care in this study. Two interventions were found to be valuable in attaining a high degree of inter-rater reliability. Washington and Moss (1988) advocated familiarizing additional raters with the theoretical perspective of the study, and familiarization with the research instrument as means to achieve higher inter-rater reliability. The nurse selected to establish inter-rater reliability of this tool worked as a clinic nurse in the disease management program and was therefore familiar with the process of disease management. This researcher spent approximately one hour informing the nurse about the objectives of the study, reviewing the theory behind disease management, and familiarizing the nurse with the study instrument. Additionally, a written copy of criteria needed to accept or reject whether a standard was met was reviewed and given to the nurse. These items became valuable during the chart review process, especially for the reviewing the portion of the records from the traditional care period when the overprinted progress note was not in use. For instance, a provider might document on the record, "feet normal." The provider may have

performed a complete comprehensive foot exam. However, there is no evidence that supports this. One reviewer who knows this provider always does a complete foot exam might accept this as evidence of adherence to ADA standards, while another who does not know this provider may not accept this as evidence. Having a written criterion helps keep reviewers' assessments reliable and similar. Future researchers that wish to use the study instrument should adapt the standards of care to answer the research questions of their particular research. Adherence to ADA guidelines items such as SMBG testing, comprehensive annual foot exam testing, self-management skills assessment, exercise addressed each visit, evidence of comprehensive diabetes education, and tobacco and alcohol assessment each visit that received a kappa coefficient less than .60 to .80 on the inter-rater reliability testing should be more explicitly defined in the written criterion of what to accept as a positive or negative response in future studies using the study instrument in order to increase instrument reliability.

Researchers should perform intra-rater reliability, inter-rater reliability, and content validity as described in this paper and the journal articles referenced. The chart reviews can be a tedious and time-consuming process if providers do not document well on their patients. Researchers should plan for adequate time to accomplish this task. Having a written set of criteria for accepting or rejecting standards will make the job go smoother. Doing a pilot study may help determine what needs to be changed on the instrument before final use.

Conclusions

While the study was unable to show the efficacy of the disease management model over the traditional primary care model in improving glycemic control, it did show that disease management was at least able to maintain good glycemic control in an Air Force population. Further studies with improved designs based on the findings of this study will help discover the effectiveness of the disease management model in improving glycemic control.

The study was able to show clinically significant improvements in 18 ADA standards of care during the disease management care period of the study. Eight of these eighteen standards also demonstrated statistical significance despite a small sample size ($n = 28$). Further studies with a sufficiently large sample need to be done to document statistically significant gains in adherence to ADA standards of care through disease management programs.

This study doesn't directly address the belief that disease management can save money and improve lives compared to the traditional primary care model. However, if it is accepted that adhering to ADA standards equates with improved patient care and long-term cost savings, then further studies are needed in this area.

Importance of Disease Management Programs to Nursing Practice

The targeted treatment, care planning, outcomes measurement, and cost-efficiency of disease management has an appeal to healthcare administrators. Reeder (1999) has suggested that the unique skills of the nursing profession make nurses especially qualified to work within and manage disease management programs. At the study facility the

nurses were the focal hub around which the disease management program revolved. A senior nurse was the Chief of Disease Management, a clinic nurse was champion for the diabetes disease management program, nurses were on the committee to develop clinical guidelines, reviewed patient charts to obtain baseline CQI data, and nurses coordinated the education process leading up to implementation of disease management. As members of the disease management team, nurses coordinated diabetes care between team members, served as patient educators, evaluated patients' diabetes needs prior to provider appointments, served as patient advocates, maintained the CQI database and provided feedback to disease management team members. Nutrition, pharmacy, and lab personnel also served as valuable members of the team. Due to the smaller numbers of these personnel and their specific duties, these personnel were unable to serve in all the roles for which nurses are uniquely suited. Provider staff served in a valuable advisory role and their support for the program and use of the clinical guidelines were essential to disease management function. All team members served a vital role but the unique skills and roles of the clinic nurses were the foundation to make the program work.

Summary

Disease management is a new way of performing patient care that is especially valuable in the management of diseases that involve high levels of patient volume, overall cost, variation in care delivery, risk to patients, and a projected ability to make significant improvements (Gunter et al., 1996). Findings from this study show promising evidence that disease management increases provider adherence to ADA standards of care, and may also be a valuable tool to improve patients' glycemic control in the Air

Force setting. Further studies need to be done using larger samples to document the role of disease management in improving glycemic control and provider adherence to ADA guidelines in all clinical settings. Studies also need to be done to document the role of disease management in reducing costs and improving the quality of life for diabetes patients.

REFERENCES

American Diabetes Association (1999). American Diabetes Association: Clinical practice recommendations 1999. Diabetes Care, 22 (Supplement 1), S1-S114.

American Diabetes Association (1999a). Diabetes facts and figures. [On-line]. Available: http://www.diabetes.org/ada/facts.asp

American Diabetes Association (1999b). Learn more about ADA: About ADA. [On-line]. Available: http://www.diabetes.org/ada/info.asp

American Diabetes Association (1999c). Position statement: Diabetic nephropathy. Diabetes Care, 22 (Supplement 1), S66-S69.

American Diabetes Association (1999d). Position statement: Implications of the diabetes control and complications trial. Diabetes Care, 22 (Supplement 1), S24-S26.

American Diabetes Association (1999e). Position statement: Implications of the United Kingdom prospective diabetes study. Diabetes Care, 22 (Supplement 1), S27-S31.

American Diabetes Association (1999f). Position statement: Screening for type 2 diabetes. Diabetes Care,22 (Supplement 1), S20-S23.

American Diabetes Association (1999g). Position statement: Standards of medical care for patients with diabetes mellitus. Diabetes Care, 22 (Supplement 1), S32-S41.

American Diabetes Association (2000). American Diabetes Association: Clinical practice recommendations 2000. Diabetes Care, 23 (Supplement 1), S1-S116.

Anderson, R. M., Donnelly, M. B., Gressard, C. P., & Dedrick, R. F. (1989). Development of diabetes attitude scale for health-care professionals. Diabetes Care, 12, 120-127.

Aubert, R. E., Herman, W. H., Waters, J., Moore, W., Sutton, D., Peterson, B. L., Bailey, C. M., & Koplan, J. P. (1998). Nurse case management to improve glycemic control in diabetic patients in a health maintenance organization. Annals of Internal Medicine, 129, 605-612.

Barker, L. R., Burton, J. R., & Zieve, P. D. (1999). Principles of ambulatory medicine (5th ed.) (pp. 1053 – 1057). Baltimore: Williams and Wilkins.

Bernard, A. M., Anderson, L., Cook, C. B., & Phillips, L. S. (1999). What do internal medicine residents need to enhance their diabetes care? Diabetes Care, 22, 661-666.

Bodenheimer, T. (1999). Disease management: Promises and pitfalls. The New England Journal of Medicine, 340 (15), 1202-1205.

Brunner, L., & Hickey, M. E. (1997). Disease management: Lovelace Health Systems episodes of care-a case study. Best Practices and Benchmarking in Healthcare, 2 (6), 252-257.

Bureau of the Census (1995). Statistical brief: Sixty-five plus in the United States. [On-line]. Available: http://www.census.gov/population/www/socdemo/age.html

Burns, N., & Grove, S. K. (1997). The practice of nursing research: Conduct, critique, and utilization (3rd ed.) (pp. 327 – 329). Philadelphia: W. B. Saunders.

Carletta, J. (1996). Assessing agreement on classification tasks: The kappa statistic. Computational Linguistics, 22 (2) 249-254. [Online.] Available: http://www.cogsci.ed.ac.uk/~jeanc/squib.pdf

Casey, D. E., & Egede, L. E. (1999). Effect of a disease management tool on resident's compliance with American Diabetes Association standard of care for type 2 diabetes mellitus. Maryland Medical Journal, 48, 119-121.

Centers for Disease Control and Prevention (1997a). Prevention and control of influenza: Recommendations of the advisory committee on immunization practices (ACIP). Morbidity and Mortality Weekly Report, 45 (RR-5), 1-24.

Centers for Disease Control and Prevention (1997b). Prevention of pneumococcal disease: Recommendations of the advisory committee on immunization practices (ACIP). Morbidity and Mortality Weekly Report, 46 (RR-08), 1-24.

Chapin, B. L., Medina, S., Le, D., Bussell, N., & Bussell, K. (1999). Prevalence of undiagnosed diabetes and abnormalities of carbohydrate metabolism in a U.S. Army population. Diabetes Care, 22, 426-429.

Department of Defense/Veterans Administration (1999). National Quality Management Special Study: 1999 Review Plan-Diabetes. [On-line]. Available: http://www.cs.amedd.army.mil/qmo/diabetes/nqmdiab.doc

Diabetes Control and Complications Trial (DCCT) Research Group (1993). The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The New England Journal of Medicine, 329, 977-986.

Diabetes Control and Complications Trial (DCCT) Research Group (1996). Lifetime benefits and costs of intensive therapy as practiced in the Diabetes Control and Complications Trial. Journal of the American Medical Association, 276, 1409-1415.

Expert Committee on the Diagnosis and Classification of Diabetes Mellitus (1999). Committee report: Report of the expert committee on the diagnosis and classification of diabetes mellitus. Diabetes Care, 22 (Supplement 1), S5-S19.

Fihn, S. D., & McGee, S. R. (1992). Outpatient medicine (pp. 1– 5). Philadelphia: W. B. Saunders.

Franz, M. J., Etzwiler, D. D., Joynes, J. O., & Hollander, P. M. (Eds.). (1991). Learning to live well with diabetes (p. 126). Minneapolis, MN: DCI Publishing.

Gee, S. (1998). The AGEing process. Diabetes Forecast, 59, 72-74.

Gunter, M. J., Byrnes, J., Shainline, M., & Lucas, J. (1996). Improving outcomes through disease-specific clinical practice improvement teams: The Lovelace episodes of care disease management program. Journal of Outcomes Management, 3, 10-17.

Haffner, S. M., Lehto, S., Ronnemaa, T., Pyorala, K., & Laakso, M. (1998). Mortality from coronary heart disease in subjects with type 2 diabetes and in nondiabetic subjects with and without prior myocardial infarction. The New England Journal of Medicine, 339, 229-234.

Halbert, R. J., Leung, K. -M., Nichol, J. M., & Legorreta, A. P. (1999). Effect of multiple patient reminders in improving diabetic retinopathy screening. Diabetes Care, 22, 752-755.

Harris, M. I., Flegal, K. M, Cowie, C. C., Eberhardt, M. S., Goldstein, D. E., Little, R. R., Wiedmeyer, H. M., & Byrd-Holt, D. D. (1998). Prevalence of diabetes, impaired fasting glucose, and impaired glucose tolerance in U.S. adults. The Third National Health and Nutrition Examination Survey, 1988-1994. Diabetes Care, 21, 518-24.

Jackson, J. L., Strong, J., Cheng, E. Y., & Meyer, G. (1999). Patients, diagnoses, and procedures in a military internal medicine clinic: Comparison with civilian practices. Military Medicine, 164, 194-197.

Jarvis, C. (1996). Physical examination and health assessment (p. 144). Philadelphia: W. B. Saunders Company.

Joshi, M. S., & Bernard, D. B. (1999). Clinical improvement series: Classic CQI integrated with comprehensive disease management as a model for performance improvement. Journal on Quality Improvement, 25, 383-395.

Lynn, M. R. (1986). Determination and quantification of content validity. Nursing Research, 35, 382-385.

National Cholesterol Education Program (1993). Expert panel on detection, evaluation, and treatment of high cholesterol in adults (Adult Treatment Panel II). [Online]. Available: http://www.nhlbi.nih.gov/health/prof/heart/index.htm#chol

Olson, O. C. (1988). Diagnosis and management of diabetes mellitus (2nd ed.) (pp. 92- 93). New York: Raven Press.

Potter, P. A., & Perry, A. G. (1985). Fundamentals of nursing practice: Concepts and practice (p. 328). St. Louis: C. V. Mosby.

Reeder, L. (1999). Anatomy of a disease management program: Understanding the dimensions of this growing trend. Nurse Management, 30, 41-45.

Smith, N. L., Heckbert, S. R., Bittner, V. A., Savage, P. J., Barzilay, J. I., Dobs, A. S., & Psaty, B. M. (1999). Antidiabetic treatment trends in a cohort of elderly people with diabetes: The cardiovascular health study, 1989-1997. Diabetes Care, 22, 736-742.

Tiwary, C. M., & Michalek, J. E. (1995). Incidence of diabetes among dependents of the U.S. military forces admitted to U.S. Army treatment facilities, 1971-1991. Diabetes Care, 18, 90-92.

UK Prospective Diabetes Study (UKPDS) Group (1998a). Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). The Lancet, 352, 832-853.

UK Prospective Diabetes Study (UKPDS) Group (1998b). Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes (UKPDS 34). The Lancet, 352, 854-865.

UK Prospective Diabetes Study (UKPDS) Group (1998c). Tight blood pressure control and risk of macrovascular and microvascular complications in type 2 diabetes (UKPDS 38). British Medical Journal, 317, 703-713.

Washington, C.C., & Moss, M. (1988). Pragmatic aspects of establishing inter-rater reliability in research. Nursing Research, 37, 190-191.

Wylie-Rosett, J., Cypress, M., & Basch, C. (1992). Diabetes quality assurance checklist: Assessment of inter-rater and intra-rater reliability. Diabetes Educator, 18, 411-415.

APPENDICES

Appendix A – Facility Clinical Practice Guidelines

Appendix B – Adherence to ADA Guidelines Assessment Checklist

Appendix C – Air Force Instruction 44-102, 1 July 1998

Appendix D – Tables of Statistical Data

Appendix E – Instrument Content Validity Documents

Appendix F – IRB Approval Forms

Appendix G – Facility Overprinted Diabetes Progress Note

APPENDIX A

FACILITY CLINICAL PRACTICE GUIDELINES

DEPARTMENT OF THE AIR FORCE
319TH MEDICAL GROUP (AMC)
GRAND FORKS AIR FORCE BASE, NORTH DAKOTA

1 October 1998

Essential Information for Clinical Guidelines and Quality Improvement
CLINICAL PRACTICE GUIDELINES FOR THE DIAGNOSIS AND MONITORING OF
DIABETES

Sources: American Diabetes Association, International Diabetes Center

1. Guidelines for Diagnosis of Diabetes -- Preferred test = Fasting Plasma Glucose (FPG)

   Normal: FPG <110 mg/dL
   Impaired Glucose Homeostasis: FPG 111-125 mg/dL
   Diabetes: FPG ≥ 126 mg/dL or Casual Plasma Glucose ≥ 200 mg/dL
   Required: Two elevated values on separate days.

2. Recommendations for Glycemic Control

		Goal	Action Suggested
Fasting / Preprandial Glucose (mg/dL)		< 120	<80 or > 140
Bedtime Glucose (mg/dL)		100-140	<100 or > 160
Hemoglobin A1C (normal = < 6%)	Type I	< 8%	> 8%
	Type II	< 7%	> 7%
	Gestational	< 6%	> 6%

3. Blood Pressure Control (for non-pregnant adults) = < 130 / < 85

4. Lipid Control (mg/dL)

   Total Cholesterol < 200
   LDL Cholesterol < 130 without known CHD, or < 100 with known CHD
   HDL Cholesterol > 35
   Triglycerides < 200

5. Quality Indicators / Exams / Teaching

	Recommended Frequency
PCM office visits*	2/yr minimum (if meeting goal) Every quarter (if not meeting goal)
HgA1C*	2/yr minimum (if meeting goal) Every quarter (if not meeting goal)
Dilated eye exam*	Annually
Urinalysis for protein*	Annually
Urine Microalbumin*	If UA negative for protein
Comprehensive foot exam*	Annually
Brief inspection	Every regular visit
Lipid Profile*	Annually–adults; Every 5yrs-children
EKG*	Minimum baseline for adults only
Blood pressure	Every regular visit
Weight	Every regular visit
Preventive Care Counseling	Every regular visit
Nutritional Assessment/Dietary counseling*	Preferred annually
Home Glucose Monitoring Training*	Documented in medical record
General Diabetes Education Classes	Every 3 years

(* = ADA required and/or monitored item)

APPENDIX B

ADHERENCE TO ADA GUIDELINES ASSESSMENT CHECKLIST

ADHERENCE TO ADA GUIDELINES ASSESSMENT CHECKLIST

Today's Date _____ Reviewer_____

Circle One Traditional Care Disease Management Care (start date_____)

Demographic Information

Pt initials _____ Last 4 SSN _____ Age _____ Sex_____ Ht _____

Ethnicity_____Diabetes type: 1 or 2 (circle) Date diagnosis_____

Treatment (circle all that apply): Nutrition /ExerciseTherapy Oral hypoglycemics Insulin

Adherence to ADA Guidelines	**6 months**		**Date/Result**	**12 months**	**Date/Result**
1. Routine Diabetes Visits (semi-annually)	Y	N		Y	N
2. Weight (each visit)	Y	N	_____	Y	N_____
3. Blood Pressure (each visit)	Y	N	_____	Y	N_____
4. SMBG Results Addressed(each visit)	Y	N		Y	N
5. Comprehensive Foot Exam (annually)				Y	N
6. Microalbuminuria Screen-UA if Proteinuria documented (annually)				Y	N
7. Fasting Lipid Profile (annually-adults, see notes on back)				Y	N_____
8. HbA1C (Baseline Date/Result_____) (twice per year-pt meeting goals)	Y	N	_____	Y	N_____
9. Nutritional Assessment (each visit)	Y	N		Y	N
10. Exercise Addressed (each routine visit)	Y	N		Y	N
11. Self Mgmt Skills/Knowledge Assessed (annually)				Y	N
12. Retina Exam by Optometry/Ophth (annually)				Y	N
13. Evidence of Comprehensive Self-Management Class – Date(s)				Y	N _____
14. Individualized Nutrition Recommendation - Date(s) (Preferably by a registered dietician)				Y	N_____
15. Baseline EKG (adults)				Y	N

Items 16 – 18 continued on next page

Year 2000 New Standards				
16. Annual Flu Vacc Recommended (annually)			Y	N
17. One-Time Pneumococcal Vacc recommended			Y	N
18. Tobacco & Alcohol Assessment (Each routine visit)	Y	N	Y	N

Notes for Items 1-18

- Items 1-12 refer to routine diabetes provider visits. A + / - variance of 1 month will be accepted for these visits to allow for scheduling difficulties in obtaining appointments. Circle "Y" if date of metric is within 1 month. Give credit for compliance if provider clearly wrote order for lab studies or procedures in chart, even if results not on the chart (patients may receive part of their care at other facilities, and those visit records may not be part of the reviewed record).
- Item 5 – Acceptable parameters for foot exam must include documented vascular status, skin integrity, structure/biomechanics, and assessment of protective sensation. Assessment may be done by a nurse as well as a provider.
- Item 7 – If no annual lipid profile within the 1-year study period for traditional or disease management care, mark the date and results of previous lipid profile. If lipid results are low risk, i.e. LDL <100 mg/dL, HDL > 45 mg/dL, triglycerides < 200 mg/dL, guidelines state lipid profile can be repeated every 2 years.
- Item 13, 14 – Frequency depends upon patient needs. Patient should have received these care items at least once since diagnosis, with updates as needed to maintain treatment goals.

Notes for Items 1-18 continued

- Item 15 – patient should have had EKG upon initial exam. Should be an EKG in medical record.
- Exercise, nutrition assessment, self-management skills, and tobacco/alcohol assessments will receive credit if done by any member of healthcare team.
- Items 16-18 – These items will be tallied, but evaluated separately from the other standards of care since they were not in the ADA guidelines during the study time period.

APPENDIX C

AIR FORCE INSTRUCTION 44-102, 1 July 1998

COMMUNITY HEALTH MANAGEMENT, COVER SHEET

Air Force Instruction 44-102, 1 July 1998 Community Health Management, Cover Sheet and Page 11.

BY ORDER OF THE SECRETARY OF THE AIR FORCE

AIR FORCE INSTRUCTION 44-102

1 JULY 1998

Medical

COMMUNITY HEALTH MANAGEMENT

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

NOTICE: This publication is available digitally on the SAF/AAD WWW site at: http://afpubs.hq.af.mil. If you lack access, contact your Publishing Distribution Office (PDO).

OPR: AFMOA/SGOC
(Lt Col Arnyce R. Pock)
Supersedes AFI 44-102, 1 February 1996.

Certified by: AFMOA/SGO
(Lt Gen Charles H. Roadman, II)
Pages: 64
Distribution: F

This instruction implements AFPD 44-1, *Medical Operations,* and provides guidance for the organization and delivery of community based, prevention focused, healthcare. It implements various publications of Department of Defense (DoD) recognized professional medical organizations, the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), and appropriate health and safety agencies. This instruction applies to all personnel assigned to or working in Air Force Medical Treatment Facilities (MTF) and Aeromedical Evacuation units, including Reserve and Guard personnel during their active duty periods, civilian, contract, volunteer personnel and trainees. Submit all supplements to this Air Force Instruction (AFI) to AFMOA/SGOC for approval. Send comments and suggested improvements on AF Form 847, **Recommendation for Change of Publication,** through channels, to AFMOA/SGOC, 110 Luke Avenue, Suite 400, Bolling AFB DC 20332-7050.

SUMMARY OF REVISIONS

This instruction represents a major revision of AFI 44-102, previously known as *Patient Care and Management of Clinical Services.* This AFI facilitates the incorporation of principles of managed care and community health management into everyday practice. It also includes the Surgeon General's guidance on the use of anorectic drug therapy and the management of healthcare workers infected with Hepatitis B. *NOTE:* In accordance with the Objective Medical Group (OMG) the designation of MFC (Medical Facility Commander) has been replaced by the use of MDG/CC (Medical Group Commander). Nonetheless, the guidance contained in this AFI still applies to commanders of facilities that are not large enough to merit a group designation.

cesses must utilize these resources in the most efficient and cost-effective manner to achieve the AFMS goals of delivering best value healthcare.

1.6.2. The MDG/CC will establish an ongoing process to assess the health status of their beneficiaries using the Health Enrollment Assessment Review (HEAR).

1.7. Clinical Practice Guidelines (CPGs):

1.7.1. Clinical Practice Guidelines (CPGs) are recommendations for the optimal sequence of actions or decisions (strategies) to solve clinical problems. They are established in order to optimize the delivery of healthcare throughout the medical service and are central to the implementation of total disease management.

1.7.1.1. MTF's will incorporate the use of evidence based clinical practice guidelines into clinical practice for high volume, high cost, high risk, and/or problem prone areas. Guidelines (ex. asthma management) from nationally recognized professional/scientific organizations are well suited for this purpose, and may be modified for local use.

1.8. Critical Pathways.

1.8.1. Critical Pathways are complementary to CPGs and represent detailed, multi-disciplinary plans for translating healthcare strategies into effective actions tailored to the needs of individuals or a population. Critical Pathways are designed to enhance provider proficiency/efficiency, improve clinical outcomes, and reduce cost.

1.8.1.1. MTF's will develop or adapt, and implement critical pathways for the most prevalent, costly, and/or problem prone services required by their served community.

1.8.1.2. Critical Pathways will be used as benchmarks for evaluating and improving some aspects of organizational performance.

1.9. Case Management.

1.9.1. Each MTF will develop plans to ensure a case management approach for those patients/families with extensive and/or complex needs.

1.9.1.1. Case managers coordinate healthcare services across an entire spectrum of disease and dysfunction that may impact an individual, from evaluation and diagnosis through multi-modality treatment and into rehabilitation. Case management seeks to prevent or lessen the potential adverse impact of future events through an emphasis on preventive strategies and to optimize patient functioning while preserving resources.

1.10. Discharge Planning.

1.10.1. Each MTF will establish a formal program to identify and solve post-hospital needs in accordance with Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) guidelines.

1.10.1.1. Discharge planning will be conducted by both inpatient and ambulatory surgery facilities to the extent appropriate for each patient.

1.10.2. The Chief, Medical Staff.

1.10.2.1. Monitors discharge planning activities by overseeing the utilization review process.

APPENDIX D

TABLES OF STATISTICAL DATA

Table D1

Pearson's Correlation Coefficients for Chart Review Scores (n = 28)

	Intra-rater Reliability Time 1 vs. Time 2 r	Inter-rater Reliability Reviewer 1 vs. Reviewer 2 r
Date of Semiannual Visit Traditional Care	1.0	1.0
Date of Annual Visit Traditional Care	1.0	1.0
Date of Semiannual Visit Disease Mgmt	1.0	1.0
Date of Annual Visit Disease Mgmt	1.0	1.0
Weight at Traditional Care Semiann Visit	1.0	1.0
Weight at Traditional Care Annual Visit	1.0	1.0
Weight at Disease Mgmt Semiann Visit	1.0	1.0
Weight at Disease Mgmt Annual Visit	1.0	1.0
Blood Pressure at Traditional Care Semiann Visit	1.0	1.0
Blood Pressure at Traditional Care Annual Visit	1.0	1.0
Blood Pressure at Disease Mgmt Semiann Visit	1.0	1.0
Blood Pressure at Disease Mgmt Annual Visit	1.0	1.0
HgbA1C Baseline Traditional Care	1.0	1.0
HgbA1C Semiannual Traditional Care Visit	1.0	1.0
HgbA1C Annual Traditional Care Visit	1.0	1.0

(table continues)

Table D1 (continued)

Pearson's Correlation Coefficients for Chart Review Scores (n = 28)

	Intra-rater Reliability	Inter-rater Reliability
	Time 1 vs. Time 2	Reviewer 1 vs. Reviewer 2
	r	r
HgbA1C Baseline Disease Mgmt	1.0	1.0
HgbA1C Semiannual Disease Mgmt Visit	1.0	1.0
HgbA1C Annual Visit Disease Mgmt	1.0	1.0

Note. All correlations are significant at the p = .01 level (2-tailed).

Table D2

Kappa Analysis for Chart Review Scores (n = 10)

	Intra-rater Reliability Time 1 vs. Time 2 kappa	Inter-rater Reliability Reviewer 1 vs. Reviewer 2 kappa
Semiannual Visit Traditional Care	1.0	1.0
Annual Visit Traditional Care	1.0	1.0
Semiannual Visit Disease Management	1.0	1.0
Annual Visit Disease management	1.0	1.0
Wt Check Semiann Visit Traditional Care	1.0	1.0
Wt Check Annual Visit Traditional Care	1.0	1.0
Wt Check Semiann Visit Disease Mgmt	1.0	1.0
Wt Check Annual Visit Disease Mgmt	1.0	1.0
BP Checked Semiann Visit Traditional Care	1.0	1.0
BP Checked Annual Visit Disease Mgmt	1.0	1.0
BP Checked Semiann Visit Disease Mgmt	1.0	1.0
BP Checked Annual Visit Disease Mgmt	1.0	1.0
SMBG Addressed Semiann Traditional Care	**.6** (p=. 04))	**.4** (p=. 11)
SMBG Addressed Annual Traditional Care	1.0	**.28** (p=. 20)
SMBG Addressed Semiann Disease Mgmt	1.0	**.4** (p=. 11)
SMBG Addressed Annual Visit Disease Mgmt	1.0	**.28** (p=. 20)

(table continues)

Table D2 (continued)

Kappa Analysis for Chart Review Scores (n = 10)

	Intra-rater Reliability Time 1 vs. Time 2 kappa	Inter-rater Reliability Reviewer 1 vs. Reviewer 2 kappa
Comprehensive Foot Exam Traditional Care	1.0	**.52** (p=. 10)
Comprehensive Foot Exam Disease Mgmt	1.0	1.0
Microalbumin Screen Traditional Care	1.0	1.0
Microalbumin Screen Disease Mgmt	1.0	1.0
Lipid Profile Traditional Care	1.0	1.0
Lipid Profile Disease Management	1.0	1.0
HgbA1C Checked Semiann Traditional Care	1.0	1.0
HgbA1C Checked Annual Disease Mgmt	1.0	1.0
HgbA1C Checked Semiann Disease Mgmt	1.0	1.0
HgbA1C Checked Annual Disease Mgmt	1.0	1.0
Nutrition Assessed Semiann Traditional Care	1.0	1.0
Nutrition Assessed Annual Traditional Care	**.72** (p=. 02)	1.0
Nutrition Assessed Semiann Disease Mgmt	1.0	**.6** (p= .04)
Nutrition Assessed Annual Disease Mgmt	1.0	1.0
Self Mgmt Skills Assessed Traditional Care	1.0	**.62** (p= .04)
Self Mgmt Skills Assessed Disease Mgmt	1.0	**.20** (p= .49)

(table continues)

Table D2 (continued)

Kappa Analysis for Chart Review Scores (n = 10)

	Intra-rater Reliability Time 1 vs. Time 2 kappa	Inter-rater Reliability Reviewer 1 vs. Reviewer 2 kappa
Exercise Addressed Semiann Traditional Care	1.0	**.6** (p=. 06)
Exercise Addressed Annual Traditional Care	1.0	**.78** (p= .01)
Exercise Addressed Semiann Disease Mgmt	1.0	**.4** (p=. 11)
Exercise Addressed Annual Disease Mgmt	1.0	1.0
Annual Retina Exam Traditional Care	1.0	1.0
Annual Retina Exam Disease Mgmt	1.0	1.0
Compr. Diabetes Education Traditional Care	1.0	**.78** (p=. 01)
Compr. Diabetes Education Disease Mgmt	1.0	**.21** (p=. 49)
Indiv. Nutr. Recommendation Traditional Care	1.0	1.0
Indiv. Nutr. Recommendation Disease Mgmt	1.0	**.78** (p=. 01)
Baseline EKG Traditional Care	1.0	1.0
Baseline EKG Disease Mgmt	1.0	1.0
Annual Flu Shot Recommended Traditional Care	1.0	1.0
Annual Flu Shot Recommended Disease Mgmt	1.0	1.0

(table continues)

Table D2 (continued)

Kappa Analysis for Chart Review Scores (n = 10)

	Intra-rater Reliability Time 1 vs. Time 2 kappa	Inter-rater Reliability Reviewer 1 vs. Reviewer 2 kappa
One-time Pneumococc Recomm. Trad Care	1.0	1.0
One-time Pneumococc Recomm. Disease Mgmt	1.0	1.0
Tobacco & Alcohol Assess SemiannTrad Care	1.0	**.62** (p= .04)
Tobacco & Alcohol Assess Annual Trad Care	1.0	1.0
Tob. & Alcohol Assess Semiann Disease Mgmt	1.0	**.58** (p= .07)
Tob. & Alcohol Assess Annual Disease Mgmt	1.0	**.41** (p= .11)

Note. All kappa values significant p = .002 level excepting as noted in parentheses next to differing values (in bold).

APPENDIX E

INSTRUMENT CONTENT VALIDITY DOCUMENTS

Instrument Content Validity Documents

ADHERENCE TO ADA GUIDELINES CHECKLIST
Accuracy of Indicators Evaluation

ITEM: Instruction sheet-Cover letter
PURPOSE: Assess content validity of study instrument

ATTENTION DIABETES EXPERT:

I request your assistance as an expert in the field of diabetes care to help establish the content validity of my assessment tool-the ADHERENCE TO ADA GUIDELINES CHECKLIST. The instrument will be used in my thesis research study entitled "The Effects of a Disease Management Program on Glycemic Control and Adherence to American Diabetes Association Guidelines in Two Air Force Populations." The instrument will be used to collect data on adherence to ADA standards of care in the diabetes populations for one year prior to, and one year following entry into a diabetes disease management program.

Please review the study instrument and complete the Accuracy of Indicators evaluation form. On the back of the form please also make any comments or suggestions under EVALUATORS SUGGESTIONS.

Return your completed form to me in the enclosed self-addressed envelopes. In order to meet the May IRB at Malcolm Grow Medical Center, Andrews Air Force Base, I need to submit my proposal the 3rd week of April. Your input is vital. Please return the completed forms as soon as possible.

Thank you for your time and effort. Your support is greatly appreciated. If you are interested, I will gladly provide you with a copy of the final study instrument or any information regarding the study.

LAUREN F. AASE, Capt, USAF, NC

626 Tweed Way, Landover, MD 20785
301-333-9287
aasel@worldnet.att.net

Enclosures:

1. Cover Letter
2. Proposal Abstract
3. ADHERENCE TO ADA GUIDELINES ASSESSMENT CHECKLIST
4. ADHERENCE TO ADA GUIDELINES ASSESSMENT CHECKLIST Accuracy of Indicators Evaluation
5. Accuracy of Indicators Evaluation – Reference Pages
6. Photocopies of pages from American Diabetes Association: Clinical Practice Recommendations 2000
7. Self-addressed envelope to return completed form

ACCURACY OF INDICATORS EVALUATION

INSTRUCTIONS: Please evaluate the standards of care indicators in items 1-18 on the ADHERENCE TO ADA GUIDELINES ASSESSMENT CHECKLIST and rate how accurately each indicator reflects the standards of care as published in "American Diabetes Association: Clinical Practice Recommendations 2000." Be sure to read the information on the back of the ADHERENCE TO ADA GUIDELINES CHECKLIST. You may use the attached reference pages to the American Diabetes Association Guidelines: Clinical Practice Recommendations.

4 = Very Accurately 3 = Accurately 2 = Somewhat Accurately 1 = Not Accurately

Circle the number representing your choice.

Minimum Standard of Care Indicator	Accuracy of Indicator
1. Routine Diabetes Visits (semi-annually)	4 3 2 1
2. Weight Measurement (each visit)	4 3 2 1
3. Blood Pressure (each visit)	4 3 2 1
4. Self Monitored Blood Glucose Results addressed (each visit)	4 3 2 1
5. Comprehensive Foot Exam (Annually)	4 3 2 1
6. Microalbuminuria Screen -UA if Proteinuria documented (Annually)	4 3 2 1
7. Fasting Lipid Profile (Annually-adults unless low risk)	4 3 2 1
8. HbA1C (Twice per year minimum-pt meeting goals)	4 3 2 1
9. Nutritional Assessment (Each routine visit)	4 3 2 1
10. Exercise Addressed (each routine visit)	4 3 2 1
11. Self Management Skills/Knowledge Assessed (annually)	4 3 2 1
12. Retina Exam by Optometrist/Ophthalmologist (Annually)	4 3 2 1
13. Evidence of attending a Comprehensive Self-Management Class	4 3 2 1
14. Individualized Nutrition Recommendation (Preferably by a registered dietician)	4 3 2 1
15. Baseline EKG-Adults (at least once)	4 3 2 1
YEAR 2000 NEW STANDARDS	
16. Annual Flu Vaccine Recommended (Annually)	4 3 2 1
17. One-time Pneumococcal Vaccine Recommended	4 3 2 1
18. Tobacco and Alcohol Assessment (Each Routine visit)	4 3 2 1

19. The CHECKLIST as a whole reflects ADA standards of care. 4 3 2 1
Evaluators please comment on back of form.

Please comment below on individual items that you marked "1" or "2" as to how those items could be improved to better reflect ADA standards, or if you feel that item should be removed altogether, state why. Thank you.

EVALUATORS SUGGESTIONS/COMMENTS:

NAME _____

TITLE _____

EMPLOYER_____

E-MAIL OR TELEPHONE_____

EVALUATOR'S SCORES FOR ACCURACY OF INDICATORS

Adherence to ADA Guidelines Assessment Checklist (Revised Form)

ADA Standard of Care Indicators — Scores by Rater	#1	#2	#3	#4
1. Routine Diabetes Visits (semi-annually)	4	4	4	4
2. Weight Measurement (each visit)	4	4	4	3
3. Blood Pressure (each visit)	4	4	4	4
4. Self Monitored Blood Glucose Results addressed (each visit)	4	4	4	3
5. Comprehensive Foot Exam (Annually)	4	4	4	3
6. Microalbuminuria Screen -UA if Proteinuria documented (Annually)	4	4	4	4
7. Fasting Lipid Profile (Annually-adults unless low risk)	4	4	4	3
8. HbA1C (Twice per year minimum-pt meeting goals)	4	4	4	4
9. Nutritional Assessment (Each routine visit)	4	4	4	3
10. Exercise Addressed (each routine visit)	4	4	4	3
11. Self Management Skills/Knowledge Assessed (annually)	4	4	4	4
12. Retina Exam by Optometrist/Ophthalmologist (Annually)	4	4	4	3
13. Evidence of attending a Comprehensive Self-Management Class	4	4	4	3
14. Individualized Nutrition Recommendation (Preferably by a registered dietician)	4	4	4	3
15. Baseline EKG-Adults (at least once)	4	4	4	2
YEAR 2000 NEW STANDARDS				
16. Annual Flu Vaccine Recommended (Annually)	4	4	4	3
17. One-time Pneumococcal Vaccine Recommended	4	4	4	3
18. Tobacco and Alcohol Assessment (Each Routine visit)	4	4	4	4
19. The CHECKLIST as a whole reflects ADA standards of care.	4	4	4	4

Evaluators Suggestions: Items 13 & 14, Remove words "One-time Minimum" from the item. This was done on revised form above.

APPENDIX F

THESIS PROPOSAL APPROVAL FORMS

DEPARTMENT OF THE AIR FORCE
319TH MEDICAL GROUP (AMC)
GRAND FORKS AIR FORCE BASE NORTH DAKOTA

28 Apr 00

MEMORANUM FOR USUHS/GSN
ATTENTION CAPT LAUREN F. AASE

FROM: 319th MDG/SGH
1599 J Street
Grand Forks AFB ND 58205-6332

SUBJECT: Research Project Support

1. Your study proposal "The Effects of Disease Management on Glycemic Control and Adherence to American Diabetes Association in Two Air Force Populations" has been reviewed by this facility and is approved pending approval by the USUHS Institutional Review Board.

2. Your intermediary for access to data is:

Pamela J. Hall, Lt Col, USAF, NC
Chief, Healthcare Integration/Disease Management
319th MDG/MDSS/SGS
Grand Forks AFB ND 58205
DSN: 362-5450 Civ: (701) 747-5450

3. If you need further support from my office, please let me know at DSN 362-5545. Otherwise continue to update progress and coordinate activities through Lt Col Hall.

Janet M. Walker, Lt Col, USAF, MC
Chief of the Medical Staff

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
F. EDWARD HÉBERT SCHOOL OF MEDICINE
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799

May 24, 2000

MEMORANDUM FOR LAUREN F. AASE, GRADUATE SCHOOL OF NURSING

SUBJECT: IRB Approval of Protocol **T061BK-01** for Human Subject Use

Your research protocol entitled ***"The Effects of Disease Management on Glycemic Control and Adherence to American Diabetes Association Guidelines in Two Air Force Populations,"*** was reviewed and approved for execution on 5/23/2000 as an **exempt** human subject use study under the provisions of 32 CFR 219.101 (b)(4). This approval will be reported to the full IRB scheduled to meet on 15 June 2000.

The purpose of this study is to compare the effectiveness of the disease management model to the traditional primary care model of patient care in achieving glycemic control and adherence to American Diabetes Association standards of care. The IRB understands that this study involves a review of existing data to compare differences is diabetes treatment efficacy between traditonal primary care and disease management care in two separate Air Force diabetic populations. The IRB further understands that you will have access to a master list of patient identifying information which will be destroyed at the conclusion of data collection.

Please notify this office of any amendments you wish to propose and of any untoward incidents which may occur in the conduct of this project. If you have any questions regarding human volunteers, please call me at 301-295-3303.

Richard R. Levine

Richard R. Levine, Ph.D.
LTC, MS, USA
Director, Research Programs and
Executive Secretary, IRB

Cc: Director, Research Administration

APPENDIX G

FACILITY OVERPRINTED DIABETES PROGRESS NOTE

Facility Overprinted Diabetes Progress Note

SF 507, JUL 91, CONTINUATION SHEET

SEMI-ANNUAL / ANNUAL DIABETES CHECKUP

Circle: Type 1
Type 2

DATE: _____ Appt Time_____
PROVIDER:_____ Time In _____
Time Seen_____HT_____WT_____SEX____
Age_____ Drug Allergies_____
BP_____P_____T_____R_____

S/

Medications / Side Effects:

Annual Eye Exam Done? Y N Annual Dental Exam? Y N Tobacco Use: Y N Annual PAP? Y N
Diet: Alcohol Use: Y N Baseline EKG? Y N

Exercise:

O/ Exam:

Foot Exam – See reverse side of form
Hgb A1C – Goal_____ Date / Result _____
Microalbuminuria Screen – Date / Result _____
Lipids – Date_____ Chol_____ Trig _____ HDL _____ HDL ratio _____ LDL _____
Other labs:

Self Monitored Blood Glucose:

A/

P/ (Circle) Lipid panel Hgb A1C Microalbuminuria Screen Chemistry (specify)_____
TSH (if applicable)
Other lab:

Pt to schedule: (Circle) Dental Ophthalmology Nutrition Diabetes Education PAP HAWC

Report on **MEDICAL RECORD**	Or **Continuation of S.F.** **SF 600 Chronological Record of Medical Care**

DIABETIC FOOT SCREEN

DATE/TIME_____

Fill in the blanks with a "Y" or "N" to indicate the findings on the right or left foot.

	R	L	COMMENTS
Is there a foot ulcer now?	____	____	
Is there a history of foot ulcer?	____	____	
Is there toe deformity?	____	____	
Are the toenails thick or ingrown?	____	____	
Is there callous buildup?	____	____	
Is there swelling?	____	____	
Is there elevated skin temperature?	____	____	
Is there muscle weakness?	____	____	
Can the patient see the bottom of his/her feet?	____	____	
Is the patient wearing properly fitting shoes?	____	____	
Pedal / popliteal pulses palpable?	____	____	

RISK CATEGORY:

____0 No loss of protective sensation

____1 Loss of protective sensation with no weakness, deformity, callus, pre-ulcer, or history of ulceration.

____2 Loss of protective sensation with weakness, deformity, pre-ulcer, or callus, but no history of ulceration.

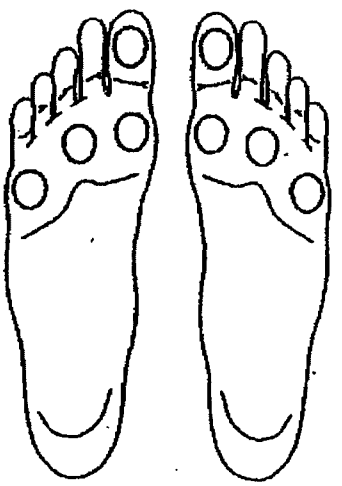
____3 History of plantar ulceration.

Indicate the level of sensation in the circles on the foot:

⊕ = Can feel the 10 gm nylon filament.

⊖ = Cannot feel the 10 gm nylon filament.

Draw in: Callus Pre-ulcer Ulcer (note width/depth in cm)



Right Foot Left Foot

Label Skin conditions: R- Redness, S- Swelling, W- Warmth, D- Dryness, M- Maceration

Physician/ Nurse Signature (Continue on reverse side)

PATIENT'S IDENTIFICATION If typed or written give: Name last, first, middle, grade, Rank, and hospital or medical facility

REGISTER NO. | WARD NO.

REPORT ON _____ OR CONTINUATION OF _____

Medical Record
Standard Form 507
319TH Medical Group Overprint, SGOMF, 1244